

# EXHIBIT 2

C. Bryce Bowling, M.D.

1           IN THE UNITED STATES DISTRICT CIRCUIT  
2           FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
3           CHARLESTON DIVISION

4           IN RE: ETHICON INC., PELVIC                    ) Master File  
5           REPAIR SYSTEM PRODUCTS LIABILITY        ) No.  
6           LITIGATION                                    ) 2:12-MD-02327  
7           \_\_\_\_\_                                        ) MDL No. 2327  
8    )  
9           THIS DOCUMENT RELATES TO ALL                ) JOSEPH R. GOODWIN  
10          WAVE 8 AND SUBSEQUENT WAVE CASES        ) U.S. DISTRICT JUDGE  
11          AND PLAINTIFFS                                )  
12          \_\_\_\_\_                                        )

13          In Re: General re  
14          Prolift/Prolift+M/Gynemesh &  
15          TVT/TVT-Exact/TVT-O

16                           ORAL DEPOSITION OF

17                           C. Bryce Bowling, M.D.

18                           Friday, September 28, 2018

19                           9:00 A.M.

20                           University of Tennessee Medical Center

21                           1930 Alcoa Highway

22                           Knoxville, Tennessee

23                           Georgette H. Mitchell  
24                           Registered Professional Reporter

Page 2	Page 4
<p>1 APPEARANCES OF COUNSEL:  2 ON BEHALF OF THE PLAINTIFF:  3 Ann Gayle, Esquire  4 Aylstock, Witkin, Kreis &amp; Overholtz, PLLC  5 17 East Main Street  6 Suite 200  7 Pensacola, Florida 3202  8 850.202.1010  9 Agayle@awko.law.com  10 ON BEHALF OF THE DEFENDANTS:  11 Jordan N. Walker, Esq.  12 Butler Snow LLP  13 1020 Highland Colony Parkway  14 Suite 1400  15 Ridgeland, Mississippi 39157  16 601.948.5711  17 Jordan.walker@butlersnow.com  18 Also Present:  19 (Telephonically)  20  21 James Lyle, Esq.  22  23  24</p>	<p>1 I N D E X (Continued)  2 Exhibit 12-A - Resume supplied on September  3 28/2018. 90  4 Exhibit 20 - Medical License. 127  5 Exhibit 13 - FDA Article entitled Update on  6 serious complications associated with  7 transvaginal placement of surgical mesh for  8 pelvic organ prolapse, FDA safety  9 communication. 128  10 Exhibit 14 - Article entitled Safety of  11 Vaginal Mesh Surgery Versus Laparoscopic Mesh  12 Sacropexy for Cystocele Repair: Results of  13 the Prosthetic Pelvic Floor Repair Randomized  14 Controlled Trial. 146  15 Exhibit 15 - Urogynecologic Surgical Mesh:  16 Update on the safety and effectiveness of  17 transvaginal placement for pelvic organ  18 prolapse dated July 2011 from the FDA. 150  19 Exhibit 23 - POP report with markings. 155  20 Exhibit 24 - Transvaginal report with  21 markings. 155  22 Exhibit 16 - Cochrane Library Surgery for  23 women with posterior compartment prolapse  24 review. 156  25 Exhibit 17 - Document entitled Long-term  26 outcome of vaginal mesh or native tissue in  27 recurrent prolapse: A randomized controlled  28 trial. 187  29 Exhibit 22 - AUGS document entitled Update on  30 Vaginal Mesh for Prolapse and Incontinence  31 dated March 2017. 195  32 Exhibit 19 - Document entitled Elongation of  33 textile pelvic floor implants under load is  34 related to complete loss of effective  35 porosity, thereby favoring incorporation in  36 scar plates. 216  37 Exhibit 18 - Document entitled Vaginal Mesh  38 Contraction. 219</p>
Page 3	Page 5
<p>1 I N D E X  2 C. BRYCE BOWLING, M.D. 6  3 EXAMINATION BY MS. GAYLE 6  4 EXAMINATION BY MR. WALKER 225  5 EXAMINATION BY MS. GAYLE 232  6 E X H I B I T S  7 Exhibit 1 - Notice of deposition. 13  8 Exhibit 3 - Invoices. 15  9 Exhibit 3-A - Billing from August 12, 2018 to  10 September 28, 2018 to be furnished. 20  11 Exhibit 1-A - Jump Drive, retained by Ms.  12 Gayle. 21  13 Exhibit 2 - Defendants' objections and  14 responses to plaintiffs' notice to take C.  15 Bryce Bowling, M.D.'s deposition. 22  16 Exhibit 4 - Expert Report of C. Bryce Bowling  17 M.D., regarding Prolift/Prolift+M/Gynemesh. 25  18 Exhibit 5 - Reliance list relating to Exhibit 37  19 4.  20 Exhibit 6 - General Reliance List relating to 39  21 TVT, TVT-Exact and TVT-O report.  22 Exhibit 7 - Report regarding TVT/TVT 42  23 Exact/TVT-O.  24 Exhibit 10 - Richard Ellkerman's reliance 72  25 list.  26 Exhibit 11 - Dr. Ahmet Bedestani general 74  27 reliance list.  28 Exhibit 21 - Supplemental reliance list. 75  29 76  30 Exhibit 21 - Bryce Bowling Supplemental  31 General Materials List in Addition to  32 Materials Referenced in Report.  33 Exhibit 8 - Curriculum Vitae. 89  34 Exhibit 9 - Curriculum Vitae. 89  35 Exhibit 12 - Resume in 2012. 89</p>	<p>1 S T I P U L A T I O N  2 The deposition of C. BRYCE BOWLING, M.D.,  3 called as a witness at the instance of the Plaintiffs,  4 pursuant to all applicable rules, taken by agreement on  5 the 30th day of September, 2018, beginning at  6 approximately 9:19 a.m., at the University of Tennessee  7 Medical Center, 1930 Alcoa Highway, Knoxville,  8 Tennessee, before Georgette H. Mitchell, Registered  9 Professional Reporter and Notary Public, pursuant to  10 the stipulation of counsel.  11 It being agreed that  12 Georgette H. Mitchell, Registered Professional Reporter  13 and Notary Public, may report the deposition in machine  14 shorthand, afterwards reducing the same to typewriting.  15 All objections, except as to the form of  16 the question, are reserved to on or before the hearing.  17 It being further agreed that all  18 formalities as to notice, caption, certificate,  19 transmission, etc., including the reading of the  20 completed deposition by the witness and the signature  21 of the witness, are waived.  22  23  24</p>

C. Bryce Bowling, M.D.

<p style="text-align: right;">Page 6</p> <p>1 (The deposition began at 9:19 a.m.)</p> <p>2 C. BRYCE BOWLING, M.D.,</p> <p>3 having first been duly sworn, was examined and deposed</p> <p>4 as follows:</p> <p>5 EXAMINATION BY MS. GAYLE:</p> <p>6 Q. Good morning, Doctor. Thank you for your</p> <p>7 time today.</p> <p>8 A. Absolutely.</p> <p>9 Q. My name is Ann Gayle. We met just</p> <p>10 briefly just before the deposition. I'm here to take</p> <p>11 your deposition today regarding the two reports that</p> <p>12 you have issued in and what we refer to as Wave 8.</p> <p>13 You've issued a</p> <p>14 Prolift/Prolift+M/Gynemesh/TVT/TVT-O/TVT Exact report.</p> <p>15 Do you understand that I'm here to take that deposition</p> <p>16 in connection with those two reports?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Do you understand that you're</p> <p>19 sworn to tell the truth today?</p> <p>20 A. Yes.</p> <p>21 Q. I see from your testimony history that</p> <p>22 was attached and provided to the materials that we were</p> <p>23 given that you have been deposed approximately ten</p> <p>24 times; is that correct?</p>	<p style="text-align: right;">Page 8</p> <p>1 ask that you try to stick to that if I'm asking for a</p> <p>2 yes or no answer.</p> <p>3 Sometimes I might say after you maybe</p> <p>4 elaborate after yes or no, I might say move to strike.</p> <p>5 There is nothing against you for that. There's nothing</p> <p>6 personal. I'm just doing by job sort of as an</p> <p>7 attorney. Counsel may also do the same thing when he's</p> <p>8 questioning you.</p> <p>9 Again, we're just trying to keep a clean</p> <p>10 record here. So I just wanted to tell you no offense,</p> <p>11 okay?</p> <p>12 A. Sure.</p> <p>13 Q. All right. Would you please state your</p> <p>14 name, for the record.</p> <p>15 A. Chadwick Bryce Bowling.</p> <p>16 Q. Have you also been known by Bryce C.</p> <p>17 Bowling?</p> <p>18 A. No. C. Bryce Bowling.</p> <p>19 Q. C. Bryce Bowling?</p> <p>20 A. Yes.</p> <p>21 Q. Doctor, I've seen in these cases that I</p> <p>22 read you that Ethicon noticed your deposition in some</p> <p>23 of those cases and they actually noticed it with Bryce</p> <p>24 C. Bowling.</p>
<p style="text-align: right;">Page 7</p> <p>1 A. I don't know how many times I've been</p> <p>2 deposed.</p> <p>3 Q. You've been deposed as early as 2015 in</p> <p>4 the Nolan versus Ethicon case, Vandergriff versus</p> <p>5 Ethicon in 2016, Mays versus Ethicon, Gaylor versus</p> <p>6 Ethicon, Slade versus Ethicon, Allmon versus Ethicon,</p> <p>7 White versus Ethicon, Cosgray versus Ethicon, Wimberly</p> <p>8 versus Ethicon and Mays versus Ethicon. Does that</p> <p>9 sound about right?</p> <p>10 A. I think that's a sample of the</p> <p>11 depositions I've given. Not all of the depositions</p> <p>12 I've given have involved the products.</p> <p>13 Q. Okay. But certainly you've been deposed?</p> <p>14 A. Several times.</p> <p>15 Q. Several times. So you're familiar with</p> <p>16 the process?</p> <p>17 A. I am.</p> <p>18 Q. There are times today as you probably</p> <p>19 have seen in the past where counsel and I will --</p> <p>20 counsel maybe will have an objection. I would ask that</p> <p>21 you answer the question over the objection unless</p> <p>22 counsel instructs you not to answer.</p> <p>23 Of course, sometimes in my questioning I</p> <p>24 may be just looking for a yes or a no answer. I would</p>	<p style="text-align: right;">Page 9</p> <p>1 So that would have been in error; is that</p> <p>2 correct?</p> <p>3 A. Yes.</p> <p>4 Q. And you've not published under any other</p> <p>5 aliases other than Chadwick Bryce Bowling?</p> <p>6 A. I think all of my publications are under</p> <p>7 C. Bryce Bowling.</p> <p>8 Q. C. Bryce Bowling. Thank you, Doctor.</p> <p>9 And you have no other aliases?</p> <p>10 A. No.</p> <p>11 Q. You're a fellowship trained board</p> <p>12 certified urogynecologist, correct?</p> <p>13 A. Correct.</p> <p>14 Q. Does Roberta Baldrige still work in your</p> <p>15 office as office supervisor?</p> <p>16 A. No.</p> <p>17 Q. Who took her place?</p> <p>18 A. Lane Schaeffer is currently office</p> <p>19 supervisor.</p> <p>20 Q. And during the course of today as we</p> <p>21 discuss names and so forth, it might be easier for the</p> <p>22 court reporter if we just begin to just take the</p> <p>23 practice of spelling last names for her ease of</p> <p>24 reference.</p>

<p style="text-align: right;">Page 10</p> <p>1 Could you spell Miss Schaeffer's last 2 name. 3 A. I believe it's S-c-h-a-e-f-f-e-r. 4 Q. And did she handle the scheduling of the 5 deposition today? 6 A. I don't know who handled the scheduling. 7 Q. Mr. Walker is here with -- representing 8 Ethicon today. Have you met him before? 9 A. Yes. 10 Q. How many times? 11 A. Twice, I believe. 12 Q. Okay. Was it in connection with, and 13 without getting into the substance of your testimony or 14 your communications with him, was it in connection with 15 this particular deposition? 16 A. No. 17 Q. Okay. In connection with another 18 deposition? 19 A. Yes. 20 Q. Against Ethicon? 21 A. I believe so, yes. 22 Q. Were you acting as a defense expert in 23 that litigation? 24 A. I don't know if I was a defense expert.</p>	<p style="text-align: right;">Page 12</p> <p>1 your practice at that time was UT Urogynecology. Is 2 that still the name of your practice? 3 A. It is. 4 Q. You also had testified back then that UT 5 Urogynecology had been started in July of 2010; is that 6 correct? 7 A. That's correct. 8 Q. Also, Doctor, as of 2016 April, you were 9 the only practicing urogynecologist at your practice. 10 Is that still the case? 11 A. No. 12 Q. Who else is now with you? 13 A. I have Robert Elder and Michael Polin. 14 P-o-l-i-n. 15 Q. When did Dr. Elder join your practice? 16 A. It would have been, I believe, in late 17 2016. I don't know the exact date and then Dr. Polin 18 joins probably about five to six months thereafter. 19 Q. And doctor -- is Dr. Elder like yourself 20 a fellowship trained board certified urogynecologist? 21 A. He is a board certified urogynecologist. 22 He came through the ranks prior to there being 23 fellowships. 24 Dr. Polin is both board certified and</p>
<p style="text-align: right;">Page 11</p> <p>1 I think I was a treating physician. 2 Q. A treating physician? 3 A. Yes. 4 MR. WALKER: Let me clarify one thing. 5 There may have been a miscommunication. I deposed 6 Dr. Bowling at one point in the past where he was 7 a treating doctor. That's what I think he's 8 referencing right there. 9 Separate and apart from that, we've met 10 twice in connection with his expert work. 11 MS. GAYLE: Okay. Thank you for that, 12 counsel. Do you recall just for the record what 13 case that was when you deposed him? 14 MR. WALKER: No. 15 BY MS. GAYLE: 16 Q. And, Doctor, when you met twice with Mr. 17 Walker, approximately how long did you meet in 18 connection with your work for this particular general 19 expert work? 20 A. Well, in connection for this general 21 report we've only met once and that was yesterday, four 22 to five hours probably. 23 Q. Doctor, in April of 2016 in the 24 Vandergriff case you had testified that the name of</p>	<p style="text-align: right;">Page 13</p> <p>1 fellowship trained. 2 Q. Doctor, thank you for anticipating my 3 question there. Counsel may tell you not to later, but 4 it sure does speed up some things. 5 Is Jessica Dobbs still your nurse 6 practitioner? 7 A. Yes. 8 Q. Do you have any other nurse practitioners 9 at this time? 10 A. No. 11 Q. How long has Jessica been with you? 12 A. Oh, I think Jess has been there three to 13 four years. I'm going to err on the side of four 14 years. 15 MS. GAYLE: Counsel, I'm going to start 16 handing him some exhibits and I know there's a lot 17 of paper here and you probably have your own 18 copies, so maybe to sort of eliminate some of that 19 just let me know if you don't have a copy of the 20 exhibit that I might be handing the doctor. 21 I've brought you extra copies, but I 22 don't want to innidiate you. 23 MR. WALKER: Perfect. Thank you. 24 (Exhibit 1 - Notice of deposition.)</p>

<p style="text-align: right;">Page 14</p> <p>1 BY MS. GAYLE:</p> <p>2 Q. Doctor, I am handing you what's been</p> <p>3 marked, pre-marked as Exhibit 1, the notice of</p> <p>4 deposition today.</p> <p>5 Doctor, have you reviewed this document</p> <p>6 prior to today?</p> <p>7 A. Yes.</p> <p>8 Q. And, Doctor, at the end of this document</p> <p>9 basically what's marked as page seven there's a</p> <p>10 schedule.</p> <p>11 A. Yes.</p> <p>12 Q. It asks you to bring some things here,</p> <p>13 and so we'll just take it one at that time. You have</p> <p>14 several different things you brought here.</p> <p>15 A complete copy of your curriculum vitae.</p> <p>16 Did you bring that today?</p> <p>17 A. Yes.</p> <p>18 Q. And, Doctor, has this changed any from</p> <p>19 your previous curriculums that you've had, in other</p> <p>20 words?</p> <p>21 A. It gets up-dated a couple times a year.</p> <p>22 Q. Okay. Defendants recently or Ethicon,</p> <p>23 sorry, I might refer to them as defendants in this</p> <p>24 matter so you understand I'm referring to Ethicon.</p>	<p style="text-align: right;">Page 16</p> <p>1 as number two?</p> <p>2 MS. GAYLE: I'm going to come back to</p> <p>3 that.</p> <p>4 BY MS. GAYLE:</p> <p>5 Q. Okay. Doctor, so what's been marked as</p> <p>6 Exhibit 3, it looks like we have several different</p> <p>7 invoices. Now, the right hand corner has the date; is</p> <p>8 that correct?</p> <p>9 A. I'll need a copy to confirm.</p> <p>10 Q. Sure.</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And then it's your invoice number,</p> <p>13 correct?</p> <p>14 A. That must be something that's assigned by</p> <p>15 Johnson &amp; Johnson. That's an invoice number that I'm</p> <p>16 familiar with and I don't know what the number</p> <p>17 underneath that is either.</p> <p>18 Q. So the invoices that you're looking at</p> <p>19 were generated by Johnson &amp; Johnson?</p> <p>20 A. No. The invoice, this portion of the</p> <p>21 invoice was generated by me through an email and sent</p> <p>22 in to the attorneys.</p> <p>23 Q. Okay. So the substance of the invoice</p> <p>24 was generated by you?</p>
<p style="text-align: right;">Page 15</p> <p>1 Ethicon provided a copy of your resume</p> <p>2 with your recent reports in early August. Have you</p> <p>3 up-dated this resume since August?</p> <p>4 A. Well, I'm not sure if the resume that</p> <p>5 they had that they sent to you in August was my most</p> <p>6 recent or not but, no, I've not up-dated my CV since</p> <p>7 August. I'll look.</p> <p>8 I would say that this is current through</p> <p>9 the summer of this year. There may be one or two</p> <p>10 didactic sessions with the residents and faculty here</p> <p>11 at UT that are not on here, otherwise it should be</p> <p>12 fairly complete.</p> <p>13 Q. Okay. Doctor, number two is any and all</p> <p>14 documents specifically consulting agreements, invoices,</p> <p>15 and so forth.</p> <p>16 I understand that you have brought some</p> <p>17 invoices today?</p> <p>18 A. Yes.</p> <p>19 MS. GAYLE: Okay. And Madam Court</p> <p>20 Reporter, if we could just mark all of these</p> <p>21 together as Exhibit 3. I'm sorry, I'm going to</p> <p>22 jump around.</p> <p>23 (Exhibit 3 - Invoices.)</p> <p>24 MR. WALKER: Are you going to mark the CV</p>	<p style="text-align: right;">Page 17</p> <p>1 A. Correct.</p> <p>2 Q. The letterhead and whatever marking is</p> <p>3 there in the right hand corner would be from Johnson &amp;</p> <p>4 Johnson?</p> <p>5 A. Correct or from the attorney group.</p> <p>6 Q. The attorney group. And you understand</p> <p>7 that Johnson &amp; Johnson is also Ethicon, correct?</p> <p>8 A. Yes.</p> <p>9 Q. And the attorney group would be Mr.</p> <p>10 Walker's firm, Butler Snow?</p> <p>11 A. Correct.</p> <p>12 Q. And that would be the case for all of the</p> <p>13 invoices?</p> <p>14 A. I assume.</p> <p>15 Q. Okay. So it looks like you met in</p> <p>16 March 15, 2018. Do you remember who Andrew is? It</p> <p>17 says one hour meeting with Andrew.</p> <p>18 MR. WALKER: That would be an attorney</p> <p>19 from our firm.</p> <p>20 MS. GAYLE: Do you know the last name?</p> <p>21 MR. WALKER: Tharp.</p> <p>22 MS. GAYLE: Pardon?</p> <p>23 MR. WALKER: Tharp.</p> <p>24 BY MS. GAYLE:</p>

<p style="text-align: right;">Page 18</p> <p>1 Q. Then you have some invoices dated</p> <p>2 July 16th for work that you did for the month of July,</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. So I apologies. In March it looks like</p> <p>6 you had \$2,700 incurred. In July 23,400, and that was</p> <p>7 part of July, it looks like through the 16th.</p> <p>8 And the next invoice appears to be from</p> <p>9 the 17th through the 31st. Does that sound accurate,</p> <p>10 Doctor?</p> <p>11 A. Let me look at it. Yes. July 17th</p> <p>12 through July 31st.</p> <p>13 Q. For a total of 13,500?</p> <p>14 A. Yes.</p> <p>15 Q. And, Doctor, is that all that you have</p> <p>16 billed -- oh, wait, there's one more. August 15, 2018</p> <p>17 and that's from August the 2nd to August the 12th, and</p> <p>18 I'll let you have that just to double check. Does that</p> <p>19 sound accurate?</p> <p>20 A. Yes.</p> <p>21 Q. And that's for \$27,000, correct?</p> <p>22 A. Correct.</p> <p>23 Q. And, Doctor, so would it be correct to</p> <p>24 assume that any time that you have incurred from</p>	<p style="text-align: right;">Page 20</p> <p>1 you are doing other projects with Butler Snow in the</p> <p>2 Ethicon litigation?</p> <p>3 A. I'm looking at case specific reports.</p> <p>4 Q. Okay. For Wave 8 or for a future wave?</p> <p>5 A. For Wave 8 and for the Election Wave.</p> <p>6 MS. GAYLE: Okay. Counsel, I would</p> <p>7 request that we have any future billing we're</p> <p>8 going to have a placeholder that I'm going to mark</p> <p>9 as Exhibit 3-A. So any billing from August the</p> <p>10 12th up to the present date, if you will please</p> <p>11 supply that whenever it becomes available.</p> <p>12 I'll also give the court reporter a copy,</p> <p>13 unless you have any objections that you'd like to</p> <p>14 register.</p> <p>15 MR. WALKER: That's fine.</p> <p>16 MS. GAYLE: Okay. Great. Thank you. So</p> <p>17 Madam Court Reporter, we will mark 3-A as a</p> <p>18 placeholder.</p> <p>19 (Exhibit 3-A - Billing from August 12, 2018 to</p> <p>20 September 28, 2018 to be furnished.)</p> <p>21 BY MS. GAYLE:</p> <p>22 Q. And, Doctor, it looks like you've also</p> <p>23 brought some binders here today, and we will mark</p> <p>24 those. I think there is a CD that also talks -- that</p>
<p style="text-align: right;">Page 19</p> <p>1 August 12th through the present date has not yet been</p> <p>2 billed to Butler Snow?</p> <p>3 A. From August the 12th? No, there have</p> <p>4 been bills sent to Butler Snow but not for general</p> <p>5 reports.</p> <p>6 Q. Okay. So for your work and for this</p> <p>7 deposition today, how have you billed for that work</p> <p>8 through the present?</p> <p>9 A. I'm sorry?</p> <p>10 Q. So for your work, so from 8/12,</p> <p>11 August 12th, not for the work that you've done as an</p> <p>12 expert for Butler Snow, but for this particular project</p> <p>13 for Butler Snow?</p> <p>14 A. For the expert reports?</p> <p>15 Q. Yes, for the expert reports.</p> <p>16 A. Everything has been billed except for the</p> <p>17 meeting time yesterday.</p> <p>18 MR. WALKER: We're talking about the</p> <p>19 general reports?</p> <p>20 MS. GAYLE: For the general reports. Not</p> <p>21 any case specific work, but these general reports.</p> <p>22 THE WITNESS: Correct.</p> <p>23 BY MS. GAYLE:</p> <p>24 Q. So just to clarify the record, Doctor,</p>	<p style="text-align: right;">Page 21</p> <p>1 also has the identical materials; is that correct?</p> <p>2 A. Jump drive.</p> <p>3 MR. WALKER: Can I make a suggestion, and</p> <p>4 we can just put this on the record. We have</p> <p>5 brought a thumb drive that has all of the general</p> <p>6 reliance materials that we supplied and that are</p> <p>7 on his reliance list.</p> <p>8 Everything in the binders is on this jump</p> <p>9 drive. I understand he's made some notes on his</p> <p>10 report. I don't think there are any notes on the</p> <p>11 supporting documents.</p> <p>12 So what I would suggest is that we only</p> <p>13 mark the reports, not the entire binders, given</p> <p>14 that all the material is on the jump drive which I</p> <p>15 assume you want to mark.</p> <p>16 MS. GAYLE: Okay. Yes, we will</p> <p>17 definitely mark the jump drive as Exhibit 1-A, and</p> <p>18 I assume that we can talk about if there is any</p> <p>19 sort of password protection or anything like that</p> <p>20 on the break. I wouldn't assume there would be.</p> <p>21 MR. WALKER: There is a password on that</p> <p>22 and I can supply that to you.</p> <p>23 MS. GAYLE: Okay. Thank you.</p> <p>24 (Exhibit 1-A - Jump Drive, retained by Ms.</p>



C. Bryce Bowling, M.D.

<p style="text-align: right;">Page 22</p> <p>1 Gayle.)</p> <p>2 MS. GAYLE: And what we'll do, counsel,</p> <p>3 on the break, I'll look at these binders and make</p> <p>4 sure that the reports are the only things that</p> <p>5 have the marking, and we'll hold open a copy of</p> <p>6 Exhibit 1-B for a copy of the reports with any</p> <p>7 markings on there.</p> <p>8 If I find that other things have been</p> <p>9 marked, we can address it at that time, okay?</p> <p>10 MR. WALKER: Fair enough.</p> <p>11 BY MS. GAYLE:</p> <p>12 Q. And, Doctor, that would be the extent of</p> <p>13 the materials that you've brought today in connection</p> <p>14 with Exhibit 1?</p> <p>15 A. Correct.</p> <p>16 (Exhibit 2 - Defendants' objections and responses</p> <p>17 to plaintiffs' notice to take C. Bryce Bowling,</p> <p>18 M.D.'s deposition.)</p> <p>19 BY MS. GAYLE:</p> <p>20 Q. Doctor, I'm handing to you what's been</p> <p>21 marked as Exhibit 2. It's defendants' objections and</p> <p>22 responses to the requests that we have taken. Have you</p> <p>23 seen this document before?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 24</p> <p>1 A. Correct.</p> <p>2 Q. Is there any one person that you direct</p> <p>3 that bill to?</p> <p>4 A. There are three people that get copied on</p> <p>5 that, Jordan being one of them.</p> <p>6 Q. Okay. Who else?</p> <p>7 A. Nicky.</p> <p>8 MR. WALKER: Paralegals.</p> <p>9 THE WITNESS: Paralegals, and I can't</p> <p>10 remember the other one.</p> <p>11 BY MS. GAYLE?</p> <p>12 Q. And, Doctor, according to your reports,</p> <p>13 you charge \$600 per hour for the drafting and reviewing</p> <p>14 of materials. Does that sound accurate?</p> <p>15 A. That's correct.</p> <p>16 Q. You also charge \$4,000 for up to four</p> <p>17 hours and then \$6,000 exceeding four hours plus travel</p> <p>18 expenses; is that correct?</p> <p>19 A. That's correct.</p> <p>20 Q. And you also bill at the rate of 7,500</p> <p>21 daily for any trial testimony in addition to any travel</p> <p>22 expenses; is that also correct?</p> <p>23 A. That's also correct.</p> <p>24 Q. And that holds true for both reports,</p>
<p style="text-align: right;">Page 23</p> <p>1 MS. GAYLE: And counsel, just for the</p> <p>2 sake of completeness of the record, I'm entering</p> <p>3 this as well into record. All right, Doctor, you</p> <p>4 can put that aside.</p> <p>5 MR. WALKER: Okay.</p> <p>6 BY MS. GAYLE:</p> <p>7 Q. Doctor, do you know when you completed</p> <p>8 your general reports in this case?</p> <p>9 A. No.</p> <p>10 Q. And as we discussed a moment ago the</p> <p>11 total that you would have billed would be a combination</p> <p>12 of the invoices that we looked at plus any invoices</p> <p>13 that you are yet to submit?</p> <p>14 A. Correct.</p> <p>15 Q. Have you had been paid for the amount of</p> <p>16 time you've already been billed?</p> <p>17 A. I've been paid part of it. I don't</p> <p>18 really kept track of it.</p> <p>19 Q. And again, that check would not be coming</p> <p>20 from Johnson &amp; Johnson or Ethicon, it would come from</p> <p>21 Butler Snow?</p> <p>22 A. I have no clue. It gets electronically</p> <p>23 deposited so I don't get an actual check in hand.</p> <p>24 Q. But you bill Butler Snow?</p>	<p style="text-align: right;">Page 25</p> <p>1 correct?</p> <p>2 A. Correct.</p> <p>3 (Exhibit 4 - Expert Report of C. Bryce Bowling</p> <p>4 M.D., regarding Prolift/Prolift+M/Gynemesh.)</p> <p>5 BY MS. GAYLE:</p> <p>6 Q. Doctor, I'm handing you what I have</p> <p>7 marked as Exhibit 4. Yes, counsel, it does have some</p> <p>8 highlighting. That's for the doctors ease of</p> <p>9 reference, questions that we're going to be talking</p> <p>10 about shortly.</p> <p>11 MR. WALKER: Is that his report?</p> <p>12 MS. GAYLE: Yes, it is.</p> <p>13 MR. WALKER: Which one is that?</p> <p>14 MS. GAYLE: That is the Prolift report.</p> <p>15 We can go off the record for a moment.</p> <p>16 (Off record discussion.)</p> <p>17 BY MS. GAYLE:</p> <p>18 Q. Doctor, I'm handing you what I've marked</p> <p>19 as Exhibit 4. Can you tell me what that is?</p> <p>20 A. This appears to be a copy of my general</p> <p>21 Prolift report.</p> <p>22 Q. Okay. And doctor, does this report</p> <p>23 contain each of the opinions that you've reached</p> <p>24 regarding the Prolift, Prolift+M and Gynemesh?</p>



<p style="text-align: right;">Page 26</p> <p>1 A. It does.</p> <p>2 Q. And, Doctor, there was a little confusion</p> <p>3 between, I guess, what the attorneys said and what the</p> <p>4 title of your report was and sort of -- so I just want</p> <p>5 to clarify.</p> <p>6 In Wave 8, the products that you're</p> <p>7 opining on are what products specifically?</p> <p>8 A. I think Prolift, Prolift+M, Gynemesh,</p> <p>9 TVT, TVT-O, TVT-Exact.</p> <p>10 MS. GAYLE: And, counsel, he's been</p> <p>11 designated for all six of those products; is that</p> <p>12 correct?</p> <p>13 MR. WALKER: Correct.</p> <p>14 MS. GAYLE: I just noticed your binders</p> <p>15 are marked Prolift and then TVT. Just one of</p> <p>16 those things.</p> <p>17 MR. WALKER: Those are just informal</p> <p>18 cover pages.</p> <p>19 MS. GAYLE: Thank you.</p> <p>20 BY MS. GAYLE:</p> <p>21 Q. Okay, Doctor. And you said this report,</p> <p>22 Exhibit 4, contains all of the opinions that you've</p> <p>23 reached regarding the Prolift, Prolift+M and Gynemesh?</p> <p>24 A. That's correct.</p>	<p style="text-align: right;">Page 28</p> <p>1 that?</p> <p>2 MS. GAYLE: I was going to ask him that,</p> <p>3 yes.</p> <p>4 BY MS. GAYLE:</p> <p>5 Q. Doctor, in the past you have said that</p> <p>6 possibly you had implanted Prolift as much as 800 to a</p> <p>7 thousand times. If you had to -- I know you were</p> <p>8 estimating at that time during your testimony.</p> <p>9 If you had to estimate today, how many</p> <p>10 times would you think that you have implanted the</p> <p>11 Prolift product?</p> <p>12 A. Prolift alone? Ethicon product alone?</p> <p>13 Maybe 500 would probably be a good ball park.</p> <p>14 Q. Prolift+M, how many times have you</p> <p>15 implanted that?</p> <p>16 A. I'd say less than a hundred.</p> <p>17 Q. Gynemesh?</p> <p>18 A. I don't know. We use Gynemesh not only</p> <p>19 in vaginal surgeries but we use it in abdominal</p> <p>20 sacrocolpopexies as well, so I don't have a clear</p> <p>21 accurate answer for you there.</p> <p>22 Q. Okay. And, Doctor, just so we can just</p> <p>23 go ahead and hit on it now, the TVT, how many times</p> <p>24 have you implanted the TVT?</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. Doctor, throughout this deposition to</p> <p>2 make things a little easier I might refer to them as</p> <p>3 POP products or your POP report. Can we agree to</p> <p>4 shorthand that?</p> <p>5 A. That's fine.</p> <p>6 Q. Okay. And likewise, Doctor, the TVT</p> <p>7 report, we might refer to that as the TVT report or the</p> <p>8 sling report, okay?</p> <p>9 A. Okay.</p> <p>10 Q. Doctor, is there any reason, particular</p> <p>11 reason why you chose to combine your opinions on these</p> <p>12 three products for Exhibit 4 into a single report as</p> <p>13 opposed to separating them out?</p> <p>14 A. Their similarities. There would have</p> <p>15 been a lot of redundancy otherwise.</p> <p>16 Q. Okay. Before it went off the market,</p> <p>17 would it be correct to estimate that you've implanted</p> <p>18 Prolift in patients several hundred times?</p> <p>19 A. Yes.</p> <p>20 Q. Possibly even 800 to a thousand times?</p> <p>21 A. I don't know if it's that's high.</p> <p>22 MR. WALKER: And when you say Prolift,</p> <p>23 are you referring to Prolift and Prolift+M</p> <p>24 collectively or just Prolift? Can you clarify</p>	<p style="text-align: right;">Page 29</p> <p>1 A. In excess of 2,000 times.</p> <p>2 Q. The TVT-Exact?</p> <p>3 A. I'd say probably 500.</p> <p>4 Q. And the TVT-O?</p> <p>5 A. Between 250 and 500. Those are estimates</p> <p>6 without actually counting.</p> <p>7 Q. Okay. And so, Doctor, obviously it's</p> <p>8 safe to assume you have used the Prolift in your</p> <p>9 practice. You previously testified that you began</p> <p>10 using the Prolift as early as your residency; is that</p> <p>11 correct?</p> <p>12 A. No, I don't think I began using Prolift</p> <p>13 in my residency. We may have done some senior year of</p> <p>14 residency. I can't recall. Certainly slings in</p> <p>15 residency.</p> <p>16 Q. Okay. So when is the first time that you</p> <p>17 recall using the Prolift device?</p> <p>18 A. That I recall using it? It probably</p> <p>19 would have been 2007.</p> <p>20 Q. At what facility was that?</p> <p>21 A. UAB.</p> <p>22 Q. And UAB, Doctor, is University of Alabama</p> <p>23 at Birmingham; is that correct?</p> <p>24 A. That's correct.</p>

Page 30

1 Q. And you were in Birmingham from what I  
2 can tell from your background, approximately a year; is  
3 that correct?  
4 A. No, I was there for three years.  
5 Q. Three years.  
6 A. During those three years I was involved  
7 in a fellowship that was both accredited by ABOG and  
8 ABU.  
9 Q. And one of those is the American Board of  
10 Obstetricians and Gynecology; is that correct?  
11 A. That's correct.  
12 Q. And the other is American Association of  
13 Urology?  
14 A. American Board of Urology.  
15 Q. American Board of Urology. Thank you,  
16 Doctor.  
17 Doctor, would you agree that the Prolift  
18 has a different safety and efficacy profile than the  
19 Gynemesh flat mesh?  
20 A. A different safety and efficacy profile?  
21 Are you talking about in terms of long term efficacy of  
22 the product and as it results in recurrence or what do  
23 you mean? I'm not sure.  
24 Q. Just in general, Doctor, however you want

Page 31

1 to interpret that.  
2 A. I think the safety and efficacy profile  
3 of those two products are very similar.  
4 Q. How so, Doctor?  
5 A. How so? Well, Gynemesh is the mesh that  
6 was used in Prolift, so I think its safety is well  
7 established, and efficacy studies looking at Gynemesh  
8 versus Prolift are a little bit difficult.  
9 So you can't really compare taking a  
10 sheet of Gynemesh and placing it in a transvaginal  
11 manner directly to Prolift because Prolift is a more  
12 standardized way of correcting any prolapse, whereas  
13 before we had Prolift we had thousands of doctors doing  
14 thousands of different methods trying to figure out a  
15 way to properly affix Gynemesh to decrease recurrences  
16 and to keep exposures and the other complications low.  
17 So I think it's a little bit hard to  
18 compare efficacy of those two products without a head  
19 to head study where the Gynemesh portion of it is  
20 standardized.  
21 Q. Doctor, would you agree, for example,  
22 that the Prolift kit has the trocars and the Gynemesh  
23 flat mesh did not have the trocars, correct?  
24 A. Well, Gynemesh flat mesh just comes in a

Page 32

1 box. It has to still be inserted utilizing tools, and  
2 in early adaptations of the transvaginal mesh group  
3 they actually did utilize trocars that were very  
4 similar to what's in the Prolift kit to place that  
5 Gynemesh that was also cut in an extraordinarily  
6 similar fashion to the Prolift.  
7 Q. But you would again agree that they don't  
8 come with trocars, maybe an earlier iteration did, but  
9 the Gynemesh is not in a kit, correct?  
10 A. The Gynemesh is in a box as a flat piece  
11 of mesh. It's up to the surgeon if they're going to  
12 use a portion of Gynemesh to figure out a way to  
13 deliver that mesh into its fixation, either by use of  
14 trocar or use of more invasive surgeries to get to  
15 ligaments that generally cause a little bit more  
16 bleeding and potential nerve damage compared to trocar  
17 passages.  
18 Q. Wheres the Prolift does product come in a  
19 mesh kit and includes a trocar or trocars to implant  
20 that?  
21 A. The Prolift product came in a box that  
22 had not only mesh but also trocars to assist in the  
23 delivery of the mesh.  
24 Q. Okay. And you would agree that the

Page 33

1 Gynemesh as you said came in a box and not a kit,  
2 including the trocars; correct?  
3 A. That's correct.  
4 Q. And, Doctor, can we agree that when you  
5 implant -- was implanting the Prolift versus the  
6 Gynemesh that there might be a different risk for  
7 implanting those two products?  
8 A. No --  
9 MR. WALKER: Object to form.  
10 THE WITNESS: -- I wouldn't agree with  
11 that.  
12 BY MS. GAYLE:  
13 Q. And, Doctor, you said that you've  
14 implanted the Gynemesh in an abdominal sacrocolpopexy?  
15 A. Abdominal sacrocolpopexy. I've also  
16 delivered that in laparoscopic sacrocolpopexies as well  
17 as robotics.  
18 Q. And would you agree when using the  
19 Gynemesh in that fashion that the risks are less than  
20 if you would have placed that Gynemesh in a more  
21 traditional route that was used previously?  
22 MR. WALKER: Object to form.  
23 THE WITNESS: Risk of what?  
24 BY MS. GAYLE:

<p style="text-align: right;">Page 34</p> <p>1 Q. Risk of complications?</p> <p>2 A. Which complications, because it varies.</p> <p>3 Q. Are there more complications with the</p> <p>4 Gynemesh whenever you place it with the trocars when a</p> <p>5 surgeon places it vaginally versus through the --</p> <p>6 A. Well, again --</p> <p>7 MR. WALKER: Object to form.</p> <p>8 THE WITNESS: -- it depends on what risks</p> <p>9 we're talking about. If we look at studies</p> <p>10 comparing abdominal sacrocolpopexies with</p> <p>11 transvaginal mesh placement, we find that the</p> <p>12 largest and only randomized control that I'm aware</p> <p>13 of showed similar erosion rates.</p> <p>14 So if you're talking specifically about</p> <p>15 erosions, we have a randomized controlled trial to</p> <p>16 see if the erosions are same. If you're talking</p> <p>17 about major vessel injury or bowel injury you're</p> <p>18 more likely to have a bowel injury or a vessel</p> <p>19 injury on an abdominal sacrocolpopexy than you are</p> <p>20 a transvaginal mesh kit.</p> <p>21 BY MS. GAYLE:</p> <p>22 Q. And Doctor, on the erosions that you've</p> <p>23 mentioned with the randomized controlled trial, that is</p> <p>24 the highest level of evidence for physicians, would you</p>	<p style="text-align: right;">Page 36</p> <p>1 A. Say the question again.</p> <p>2 Q. So did you discuss the facts within that</p> <p>3 report that you felt were the most important in drawing</p> <p>4 your opinions?</p> <p>5 A. I discussed the facts that I thought were</p> <p>6 important and for people that are involved in these</p> <p>7 litigations to understand from both sides.</p> <p>8 Q. What I'm getting at, Doctor, is this</p> <p>9 report contains all of your opinions that you're</p> <p>10 prepared to offer in this litigation; is that correct?</p> <p>11 A. Well, as I said, in both reports I've</p> <p>12 reserved the right to alter those. At the current time</p> <p>13 they're reflective of what my opinions are, but if</p> <p>14 there is more evidence that is put forth before trial,</p> <p>15 then I would go back and add an addendum to the report.</p> <p>16 Q. And certainly, Doctor, to date you have</p> <p>17 not added an addendum, correct?</p> <p>18 A. I have not.</p> <p>19 Q. Doctor, in terms of your decision-making</p> <p>20 when you were writing Exhibit 4, the POP report, why</p> <p>21 did you choose to cite the articles you cited?</p> <p>22 A. Well, if you pay attention to the</p> <p>23 articles that are cited in here I've actually gone to</p> <p>24 the effort of trying to make it very easy to look</p>
<p style="text-align: right;">Page 35</p> <p>1 agree to that?</p> <p>2 A. Randomized controlled trial or Cochrane</p> <p>3 review and systematic reviews.</p> <p>4 Q. And, Doctor, what randomized controlled</p> <p>5 trial are you referencing with regard to the erosion?</p> <p>6 A. Let's see if I can find it.</p> <p>7 MS. GAYLE: If we can go off the record,</p> <p>8 please.</p> <p>9 (Off record discussion.)</p> <p>10 THE WITNESS: It is a 2011 report</p> <p>11 entitled Laparoscopic Sacrocolpopexy versus Total</p> <p>12 Vaginal Mesh for Vaginal Vault Prolapse on</p> <p>13 Randomized Trial. That was published in the</p> <p>14 American Journal of Obstetrics and Gynecology.</p> <p>15 BY MS. GAYLE:</p> <p>16 Q. Who was the lead author on that?</p> <p>17 A. Maher. M-A-H-E-R.</p> <p>18 Q. Doctor, in Exhibit 4 did you discuss the</p> <p>19 facts that you felt were the most important in drawing</p> <p>20 your opinions in this report?</p> <p>21 A. I'm sorry. See, I was concentrating on</p> <p>22 which exhibit you were talking about. My Prolift</p> <p>23 report?</p> <p>24 Q. Yes, sir, that's right.</p>	<p style="text-align: right;">Page 37</p> <p>1 through these and divide them in to sections.</p> <p>2 So you'll find that the first section is</p> <p>3 Cochrane reviews, Cochrane database reviews, systematic</p> <p>4 reviews and then randomized controlled trial. So the</p> <p>5 studies that I chose to place in here were ones that</p> <p>6 were that of the highest scientific validity.</p> <p>7 I tried to stay away from small case</p> <p>8 reports and small case series and chose to -- try to</p> <p>9 stick to the most highly trusted scientific evidence</p> <p>10 that we have.</p> <p>11 (Exhibit 5 - Reliance list relating to Exhibit</p> <p>12 4.)</p> <p>13 BY MS. GAYLE:</p> <p>14 Q. Thank you, Doctor. Doctor, I'm marking</p> <p>15 now or handing you now what's been marked as Exhibit 5</p> <p>16 and this is your reliance list to Exhibit 4 and it's</p> <p>17 entitled Bryce Bowling, General Reliance List In</p> <p>18 Addition to Materials Referenced in Report.</p> <p>19 If you will look at that. And, Doctor,</p> <p>20 is that the reliance list that was initially issued</p> <p>21 with your report?</p> <p>22 A. Yes, this is the reliance list.</p> <p>23 MR. LYLE: Hello.</p> <p>24 THE COURT REPORTER: Hello.</p>

<p style="text-align: right;">Page 38</p> <p>1 MR. LYLE: This is James Lyle.</p> <p>2 MS. GAYLE: Hi, James. This is Ann</p> <p>3 Gayle. Thanks for joining us.</p> <p>4 MR. WALKER: Can with you please restate</p> <p>5 that? This is Jordan Walker with Ethicon. I</p> <p>6 don't think the court reporter and myself could</p> <p>7 understand what you had said. It sounded broken.</p> <p>8 MR. LYLE: Okay. Well, that's the reason</p> <p>9 I said something just to make sure you can hear</p> <p>10 me. Is that better?</p> <p>11 MR. WALKER: That is better. What's your</p> <p>12 name again? I'm sorry.</p> <p>13 MR. LYLE: It's James Lyle, L-y-l-e.</p> <p>14 MR. WALKER: What firm are you with, by</p> <p>15 the way?</p> <p>16 MR. LYLE: I'm with my own firm. I don't</p> <p>17 plan on participating. I just plan on listening</p> <p>18 in.</p> <p>19 MS. GAYLE: Thank you, Mr. Lyle.</p> <p>20 MR. LYLE: Thank you.</p> <p>21 BY MS. GAYLE:</p> <p>22 Q. Doctor, we're going to get back to what</p> <p>23 we were just discussing which is your reliance list and</p> <p>24 you have identified that as Exhibit 5.</p>	<p style="text-align: right;">Page 40</p> <p>1 or did Butler Snow prepare that for you?</p> <p>2 A. They prepared that based off the</p> <p>3 information that I used in my report and additional</p> <p>4 information that I asked for during the writing of</p> <p>5 those reports.</p> <p>6 Q. So this material and these lists would be</p> <p>7 the information that you specifically asked them for</p> <p>8 and then they put it in this format for you?</p> <p>9 A. No, that's not what I said. It's a</p> <p>10 portion of what was in there is material that I asked</p> <p>11 for. A portion of what's in there is material that</p> <p>12 they provided, and a portion of what is in there is</p> <p>13 material that I searched for and found on my own.</p> <p>14 Q. Okay. So it's a mix of things. Again,</p> <p>15 just to make sure I've got it right, things that you've</p> <p>16 asked for, it's a mix of things that they have provided</p> <p>17 you, and things that might be cited in your report?</p> <p>18 A. Correct.</p> <p>19 Q. In forming your opinions on the POP</p> <p>20 products in Exhibit 4, did you rely on midurethral</p> <p>21 slings and the TVT, TVT-O, TVT-Exact to form any of</p> <p>22 your opinions regarding the safety and efficacy of the</p> <p>23 Prolift?</p> <p>24 A. I don't think I relied on TVT data to</p>
<p style="text-align: right;">Page 39</p> <p>1 I assume that you have your own copy of</p> <p>2 that reliance list, is that correct, Doctor?</p> <p>3 A. I do.</p> <p>4 (Exhibit 6 - General Reliance List relating to</p> <p>5 TVT, TVT-Exact and TVT-O report.)</p> <p>6 BY MS. GAYLE:</p> <p>7 Q. Doctor, now I'm handing you what what's</p> <p>8 been marked as Exhibit 6 and it's also entitled Bryce</p> <p>9 Bowling General Reliance List In Addition to Materials</p> <p>10 Referenced in Report, and this was the reliance list</p> <p>11 that was given to us along with a copy of your</p> <p>12 TVT/TVT-Exact and TVT-O report.</p> <p>13 Do you recognize that as that exhibit,</p> <p>14 Doctor?</p> <p>15 A. I won't take the time to compare every</p> <p>16 page of this to the reliance list that is in my folder</p> <p>17 but if you're telling me that this is the one that was</p> <p>18 associated with the TVT report then I'll believe you.</p> <p>19 Q. Thank you, Doctor. And, Doctor, I've</p> <p>20 compared both Exhibit 5 and Exhibit 6 together and they</p> <p>21 appear to be exact duplicates. Is that your</p> <p>22 understanding as well?</p> <p>23 A. I don't know. I've not compared the two.</p> <p>24 Q. Doctor, did you prepare Exhibit 5 and 6</p>	<p style="text-align: right;">Page 41</p> <p>1 look at safety and efficacy of a Prolift product. I</p> <p>2 think we may have looked at some of the differences in</p> <p>3 mesh, but I don't think I used TVT data in the Prolift</p> <p>4 report.</p> <p>5 I think probably that reliance list is a</p> <p>6 culmination of both Prolift and TVT materials that have</p> <p>7 been used throughout writing both reports.</p> <p>8 Q. And, Doctor, I would ask the same</p> <p>9 question with regard to the Prolift+ M. So in forming</p> <p>10 your opinions on the Prolift + M.</p> <p>11 Did you use any -- did you rely on any</p> <p>12 midurethral sling data for the TVT, TVT-O or TVT-Exact</p> <p>13 to form any of your opinions regarding the safety and</p> <p>14 efficacy of the Prolift+M?</p> <p>15 A. I don't believe I have, no.</p> <p>16 Q. And, Doctor, the same question for</p> <p>17 Gynemesh. Did you rely on any of the sling data to</p> <p>18 form your opinions regarding the safety and efficacy of</p> <p>19 the Gynemesh product?</p> <p>20 A. Not that I'm aware of.</p> <p>21 Q. Doctor, did you in rendering your</p> <p>22 opinions on the pelvic organ prolapse products in</p> <p>23 Exhibit 4, did you rely at all on internal company</p> <p>24 documents?</p>

<p style="text-align: right;">Page 42</p> <p>1 A. I don't know if they actually -- if I</p> <p>2 actually used those in writing specific paragraphs of</p> <p>3 this report. I have reviewed several company</p> <p>4 documents.</p> <p>5 I did review over the resource monographs</p> <p>6 and instruction for use. So some of that information</p> <p>7 may be in there.</p> <p>8 Q. Doctor, if you had to estimate, how many</p> <p>9 company documents would you think that you've reviewed?</p> <p>10 A. Oh, I don't know. I think there's a</p> <p>11 pretty healthy list on the reliance list, and I would</p> <p>12 have either scanned or reviewed every one of those or</p> <p>13 at least looked at the bulk of the material in the vast</p> <p>14 majority of them. I can't estimate a number for you</p> <p>15 though.</p> <p>16 (Exhibit 7 - Report regarding</p> <p>17 TVT/TVT-Exact/TVT-O.)</p> <p>18 BY MS. GAYLE:</p> <p>19 Q. And, Doctor, in rendering your opinions</p> <p>20 on the TVT products, which you've got a copy of your</p> <p>21 report there, and we're going to mark as Exhibit 7</p> <p>22 which I'm handing you, Doctor, does that appear to be</p> <p>23 your TVT, TVT-Exact and TVT-O report?</p> <p>24 A. It does.</p>	<p style="text-align: right;">Page 44</p> <p>1 contain each of the opinions that you've reached</p> <p>2 regarding the TVT, TVT-Exact and TVT-O?</p> <p>3 A. Yes.</p> <p>4 Q. As we've asked in the -- with regard to</p> <p>5 Exhibit 4, Doctor, is there any particular reason why</p> <p>6 you choose to confine your opinions on the TVT,</p> <p>7 TVT-Exact and TVT-O in a single report as opposed to</p> <p>8 separating them out?</p> <p>9 A. Because of their similarities.</p> <p>10 Q. And can you elaborate on that, Doctor?</p> <p>11 A. Can I elaborate on the similarities?</p> <p>12 Q. The similarities between the three</p> <p>13 products.</p> <p>14 A. Well, sure. I mean they're all</p> <p>15 midurethral slings. They're all a large pore</p> <p>16 polypropylene mesh product intended to treat stress</p> <p>17 urinary incontinence.</p> <p>18 A couple of them differ only in the route</p> <p>19 of the distal ends of the sling and where those come</p> <p>20 through the skin, but they all are the same in their</p> <p>21 placement underneath the midurethra and their purpose.</p> <p>22 Q. Thank you, Doctor. In terms of your</p> <p>23 decision-making in writing the report found at</p> <p>24 Exhibit 7, why did you choose to cite the articles</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. Okay. And, Doctor, in rendering your</p> <p>2 opinions found in Exhibit 7, did you also rely on</p> <p>3 internal company documents?</p> <p>4 A. I may, like I said with the Prolift, I</p> <p>5 may have looked over and utilized some. I'm not sure</p> <p>6 exactly that there's a sentence or paragraph that</p> <p>7 relates directly to company documents, but I have</p> <p>8 reviewed several of them.</p> <p>9 Q. And if you did rely on any internal</p> <p>10 company documents, you would expect to find those</p> <p>11 internal company documents on your reliance list; is</p> <p>12 that correct, Doctor?</p> <p>13 A. That's correct.</p> <p>14 Q. Okay. Put that aside for now, Doctor.</p> <p>15 If you did review the -- as you say you</p> <p>16 reviewed the Ethicon internal documents, are there any</p> <p>17 specifically that stuck out in your head with regard to</p> <p>18 Exhibit 4, your POP opinions?</p> <p>19 A. No.</p> <p>20 Q. Are there any internal company documents</p> <p>21 that specifically stick out in your head with regard to</p> <p>22 Exhibit 7, your TVT products?</p> <p>23 A. No.</p> <p>24 Q. And, Doctor, in Exhibit 7, does Exhibit 7</p>	<p style="text-align: right;">Page 45</p> <p>1 cited in your report?</p> <p>2 A. Same reason we cited the articles in the</p> <p>3 Prolift report. If you look through there we tried our</p> <p>4 best to utilize randomized controlled trials and to use</p> <p>5 Cochrane reviews, give the highest level of scientific</p> <p>6 data that we could.</p> <p>7 We also tried to look for long term</p> <p>8 studies demonstrating ten plus years of follow-up with</p> <p>9 patients that have had midurethral slings.</p> <p>10 Q. Doctor, if you would look at Exhibit 7,</p> <p>11 Page 5, Section 2, and I've highlighted there for your</p> <p>12 ease of reference, Doctor, there is a sentence that</p> <p>13 says plaintiffs' expert, I have reviewed the expert</p> <p>14 statements of multiple plaintiffs' experts for both</p> <p>15 case specific and general reports.</p> <p>16 Do you see that, Doctor?</p> <p>17 A. Yes.</p> <p>18 Q. Doctor, what case specific reports did</p> <p>19 you rely on in forming your opinions?</p> <p>20 A. Case specific reports. They will be in</p> <p>21 the reliance list. I looked over expert opinions in</p> <p>22 both general reports and case specific reports for</p> <p>23 several of the cases that I was working on to see what</p> <p>24 the plaintiffs' claims were regarding midurethral</p>



<p style="text-align: right;">Page 46</p> <p>1 slings.</p> <p>2 Q. And, Doctor, if you could turn to your</p> <p>3 reliance list for Exhibit 7, and indicate which cases</p> <p>4 you are working on that are the case specific reports</p> <p>5 that you relied on?</p> <p>6 MR. WALKER: Object to form.</p> <p>7 BY MS. GAYLE:</p> <p>8 Q. Doctor, you said your case specific</p> <p>9 reports that you relied on, that you did rely on them,</p> <p>10 and that they should be in this list correct, Doctor?</p> <p>11 MR. WALKER: Object to form.</p> <p>12 THE WITNESS: Okay. So when you say rely</p> <p>13 on them, can you explain to me exactly what you</p> <p>14 mean?</p> <p>15 BY MS. GAYLE:</p> <p>16 Q. You said you have reviewed the expert</p> <p>17 report statements of multiple plaintiffs' experts for</p> <p>18 both case specific and general reports.</p> <p>19 What I'm trying to get to, Doctor, is</p> <p>20 which case specific reports you reviewed?</p> <p>21 A. Any that have been sent to me. I've</p> <p>22 reviewed everything that's been sent to me.</p> <p>23 Q. Do you recall what Waves, doctor?</p> <p>24 A. They would have all been Wave 8 or</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. So, Doctor, on your list you have several</p> <p>2 reports for your reliance list that are Wave 4.</p> <p>3 A. Are those general?</p> <p>4 Q. Some of them are, Doctor, and some of</p> <p>5 them are issued in specific cases such as the -- you</p> <p>6 have the Carlino case, the Huskey case, Lewis, Mullins,</p> <p>7 Ramirez, but you did review those in previous Waves,</p> <p>8 right?</p> <p>9 A. If they were general --</p> <p>10 MR. WALKER: Object to form.</p> <p>11 THE WITNESS: -- reports in previous waves</p> <p>12 I may have looked at those. I don't think that</p> <p>13 I've looked at specific case reports from Waves</p> <p>14 that I have not been involved in. I may have. I</p> <p>15 don't know.</p> <p>16 BY MR. GAYLE:</p> <p>17 Q. And, Doctor, as he said your deadline was</p> <p>18 today for designating you in any Wave 8 cases.</p> <p>19 MR. WALKER: Not Wave 8. Election Wave.</p> <p>20 BY MS. GAYLE:</p> <p>21 Q. Election Wave, Election Wave cases, and</p> <p>22 so if you've looked at case specific reports that</p> <p>23 plaintiff issued in that Wave, that would not be</p> <p>24 included on your list?</p>
<p style="text-align: right;">Page 47</p> <p>1 Election Wave cases. Case specific reports that I am</p> <p>2 involved in.</p> <p>3 Q. And with the Election Wave, what do you</p> <p>4 mean by that, Doctor?</p> <p>5 A. Well, I mean maybe you can explain that.</p> <p>6 MR. WALKER: We can talk about that off</p> <p>7 the record.</p> <p>8 MS. GAYLE: Counsel, I'm just trying to</p> <p>9 get at which case specific reports.</p> <p>10 MR. WALKER: He has not been disclosed</p> <p>11 yet as an expert in any Election Wave documents</p> <p>12 because the deadline frankly is today.</p> <p>13 So after today we had can discuss any</p> <p>14 Election Wave cases in which he's been disclosed</p> <p>15 as an expert, and he can certainly answer</p> <p>16 questions about Wave 8.</p> <p>17 BY MS. GAYLE:</p> <p>18 Q. Doctor, with regard to previous Waves,</p> <p>19 there are --</p> <p>20 A. I don't think I've reviewed any case</p> <p>21 specific reports from previous Waves.</p> <p>22 MR. WALKER: Other than Wave 8.</p> <p>23 THE WITNESS: Correct.</p> <p>24 BY MR. GAYLE:</p>	<p style="text-align: right;">Page 49</p> <p>1 A. I don't know.</p> <p>2 Q. It's not on your list?</p> <p>3 A. You're asking questions --</p> <p>4 Q. And so counsel?</p> <p>5 A. -- after I've gone over thousands and</p> <p>6 thousands and thousands of documents, and I don't have</p> <p>7 it. That's what the reliance list is for.</p> <p>8 I don't have it in my head exactly what</p> <p>9 pages I have read on what reports that I have read. So</p> <p>10 I trust the counsel to help prepare the reliance list</p> <p>11 of anything that has been emailed to me, sent to me,</p> <p>12 requested or researched by me to add to that list, but</p> <p>13 I cannot go on there and tell you which case specific</p> <p>14 report from which Wave that I reviewed for these</p> <p>15 reports.</p> <p>16 Q. I appreciate that, Doctor, but you</p> <p>17 realize my role today is to try to get to the basis of</p> <p>18 your opinions, and so I don't see any case specific</p> <p>19 reports for Wave 8 or Election Wave on your list or</p> <p>20 your supplemental reliance list.</p> <p>21 A. Okay.</p> <p>22 Q. And so if you reviewed those in</p> <p>23 connection with your opinions, we are entitled to find</p> <p>24 out that information to determine the scope or the</p>



<p style="text-align: right;">Page 50</p> <p>1 basket of information that you reviewed.</p> <p>2 A. Well, a lot of them are the same. A lot</p> <p>3 of them are the same.</p> <p>4 If you look at some of those on there we</p> <p>5 have general and case specific reports from a number of</p> <p>6 different people who essentially copy and paste their</p> <p>7 opinions from one case to another.</p> <p>8 So that may be the reason why I'm having</p> <p>9 a hard time telling you which Waves these are from and</p> <p>10 what I've reviewed because they are so similar, many of</p> <p>11 these general and case specific reports.</p> <p>12 Q. And who are you referring to when you</p> <p>13 refer to many that have copied and paste?</p> <p>14 A. I don't have specific names. They're on</p> <p>15 the reliance list there. You can see the ones that</p> <p>16 have been reviewed.</p> <p>17 Q. And, Doctor, with regard to the general</p> <p>18 reports, that would be on the reliance list or on the</p> <p>19 supplemental reliance list, the ones that you've</p> <p>20 reviewed?</p> <p>21 A. They should be on there, yes.</p> <p>22 Q. What in the general reports was important</p> <p>23 in forming your opinions?</p> <p>24 MR. WALKER: Object to form.</p>	<p style="text-align: right;">Page 52</p> <p>1 Exhibit 4?</p> <p>2 A. I don't recall. I'm sure that I have.</p> <p>3 Q. So --</p> <p>4 A. Again, these are -- these are thousands</p> <p>5 upon thousands of documents that I have reviewed in</p> <p>6 formulating my opinions.</p> <p>7 If I reviewed a general report, then</p> <p>8 okay. I may not have put it in the materials reviewed.</p> <p>9 It may be an oversight. I can't tell you for sure.</p> <p>10 Q. Okay. Doctor, again like I said, I'm</p> <p>11 basis trying to get to the basis of your opinions.</p> <p>12 A. I understand.</p> <p>13 Q. And so I thought it was odd that one says</p> <p>14 that you did review case specific and general and the</p> <p>15 other report says that you didn't.</p> <p>16 A. I wouldn't read too much into that.</p> <p>17 Q. Okay. So that might be just an error</p> <p>18 that you did rely on case specific for your Prolift?</p> <p>19 MR. WALKER: Object to form.</p> <p>20 THE WITNESS: Again, I don't remember.</p> <p>21 BY MS. GAYLE:</p> <p>22 Q. Okay. And again, you may have relied on</p> <p>23 general reports for your Prolift, but you don't know?</p> <p>24 MR. WALKER: Object to form.</p>
<p style="text-align: right;">Page 51</p> <p>1 BY MS. GAYLE:</p> <p>2 Q. What stood out?</p> <p>3 A. Let's see. Some of the things that stood</p> <p>4 out were the lack of data, lack of long term randomized</p> <p>5 controlled trial and Cochrane review data that were</p> <p>6 left off of those reports showing the long term safety</p> <p>7 and efficacy of the products.</p> <p>8 Q. Doctor, if you could turn to your</p> <p>9 Exhibit 4, which is your POP report and page five on</p> <p>10 that particular exhibit and this paragraph is similar</p> <p>11 except for two lines with regard to your sling or your</p> <p>12 Exhibit 7 report.</p> <p>13 It does not have the sentence that quote,</p> <p>14 I have reviewed the expert statements of multiple</p> <p>15 plaintiff experts for both case specific and general</p> <p>16 reports.</p> <p>17 Was that an oversight, doctor?</p> <p>18 MR. WALKER: Object to form.</p> <p>19 THE WITNESS: I don't know.</p> <p>20 BY MS. GAYLE:</p> <p>21 Q. Did you review any case specific reports</p> <p>22 for Exhibit 4?</p> <p>23 A. I don't recall.</p> <p>24 Q. Did you review any general reports for</p>	<p style="text-align: right;">Page 53</p> <p>1 A. Possibly so.</p> <p>2 BY MS. GAYLE:</p> <p>3 Q. Do you know whether you relied on general</p> <p>4 reports for your Prolift?</p> <p>5 MR. WALKER: Object to form.</p> <p>6 THE WITNESS: You're asking the same</p> <p>7 questions over and over again. I'll give you the</p> <p>8 same response. I don't know.</p> <p>9 I have reviewed so many records that I</p> <p>10 cannot give you an accurate statement of what I</p> <p>11 reviewed for each of the reports.</p> <p>12 BY MS. GAYLE:</p> <p>13 Q. So you don't know, again, I'm sorry,</p> <p>14 we're saying relied and reviewed. So let me just ask</p> <p>15 one more time to cure his objection, okay, Doctor?</p> <p>16 A. Okay.</p> <p>17 Q. Like I said, sometimes us attorneys might</p> <p>18 be going back and forth. Your counsel has objected, so</p> <p>19 I'm going to reform my question.</p> <p>20 A. Wear yourself out.</p> <p>21 Q. Okay, Doctor. So you don't know if you</p> <p>22 reviewed general reports for your Prolift report,</p> <p>23 Exhibit 4?</p> <p>24 A. Correct, I do not recall.</p>

<p style="text-align: right;">Page 54</p> <p>1 Q. Okay. And you do not recall whether or</p> <p>2 not you reviewed the case specific reports for your</p> <p>3 Prolift POP opinions in Exhibit 4?</p> <p>4 A. Correct.</p> <p>5 Q. Okay. Thank you, Doctor. Sometimes we</p> <p>6 may do that and again no offense as we talked about at</p> <p>7 the beginning of the deposition, Doctor.</p> <p>8 A. None taken.</p> <p>9 Q. Doctor, also in that paragraph on page</p> <p>10 five if you would look at Exhibit 7, and like I told</p> <p>11 you we're going to be comparing certain sections side</p> <p>12 by side to sort of eliminate some of the time and</p> <p>13 duplicity that we have today, Doctor.</p> <p>14 Exhibit 7, the second line down, first</p> <p>15 paragraph in section two starts with -- see the words</p> <p>16 ACOG that I have highlighted for your reference,</p> <p>17 Doctor?</p> <p>18 A. Yes.</p> <p>19 Q. ACOG Committee Opinions, Position</p> <p>20 Statements from the major gynecological surgical</p> <p>21 societies.</p> <p>22 That phrase, Doctor, is in Exhibit 7 but</p> <p>23 again that phrase does not appear in Exhibit 4, and so</p> <p>24 since this section talks about the materials that you</p>	<p style="text-align: right;">Page 56</p> <p>1 opinions, position statements from these different</p> <p>2 surgical societies, this is information that as a</p> <p>3 urogynecologist is common knowledge for me. These are</p> <p>4 things that have been reviewed multiple times per year.</p> <p>5 So pulling out an ACOG committee opinion</p> <p>6 and reading it at the time of the report may not be</p> <p>7 exactly how my information from those societies got</p> <p>8 into the report.</p> <p>9 This is material that I have read several</p> <p>10 times, that I have a working knowledge of, that may</p> <p>11 have been incorporated into my report where I didn't</p> <p>12 actually have the surgical society or the committee</p> <p>13 opinion open and looking at at the time.</p> <p>14 Q. And, Doctor, again these are the</p> <p>15 materials contained in this paragraph for both reports.</p> <p>16 Basically what I'm getting at is they form the basis of</p> <p>17 your opinions in each of those reports?</p> <p>18 MR. WALKER: Object to form.</p> <p>19 THE WITNESS: It is a combination of the</p> <p>20 materials that I reviewed as well as my</p> <p>21 background, training and experience in dealing</p> <p>22 with pelvic floor disorders throughout many years.</p> <p>23 So I would not say that it is all based</p> <p>24 on committee opinions, statements or documents. A</p>
<p style="text-align: right;">Page 55</p> <p>1 have reviewed, I just want to be clear, you reviewed</p> <p>2 those ACOG materials, committee opinions and position</p> <p>3 statements in connection with your opinions in the</p> <p>4 sling report in Exhibit 7, correct?</p> <p>5 A. Correct.</p> <p>6 Q. Did you also review those materials in</p> <p>7 connection with your POP opinions in Exhibit 4?</p> <p>8 A. I have.</p> <p>9 Q. And you would have relied on both of that</p> <p>10 material for both of the reports, correct?</p> <p>11 MR. WALKER: Object to form.</p> <p>12 THE WITNESS: Correct.</p> <p>13 BY MS. GAYLE:</p> <p>14 Q. You would rely on those materials for</p> <p>15 forming your opinions in Exhibit 7, correct?</p> <p>16 A. Yes.</p> <p>17 Q. And you would rely on those materials for</p> <p>18 forming your opinions in Exhibit 4, correct?</p> <p>19 A. Yes. Well, let me go back and clarify</p> <p>20 because I think we're -- I think you're sticking on</p> <p>21 some terminology here that I think is important to</p> <p>22 tease out.</p> <p>23 When you say rely upon, what I would like</p> <p>24 to clarify is that a lot of the ACOG committee</p>	<p style="text-align: right;">Page 57</p> <p>1 large portion of what I base my opinions on are</p> <p>2 training and previous education.</p> <p>3 BY MS. GAYLE:</p> <p>4 Q. Thank you, Doctor. And again we're just</p> <p>5 trying to get to the materials that you relied on for</p> <p>6 each specific report. As you said in your reliance</p> <p>7 list combined all the materials, and so we're trying to</p> <p>8 get to what differences there might be as far as that</p> <p>9 collection of materials.</p> <p>10 And I believe you may have anticipated my</p> <p>11 next question, Doctor, which is if you would look at</p> <p>12 Exhibit 4, you see that I've highlighted for your</p> <p>13 convenience the phrase other company documents.</p> <p>14 That phrase appears in your materials</p> <p>15 reviewed for Exhibit 4 whereas that phrase does not</p> <p>16 appear in your terms reviewed for Exhibit 7; is that</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. And, Doctor, would that be an oversight</p> <p>20 there?</p> <p>21 MR. WALKER: Object to form.</p> <p>22 THE WITNESS: I think you're asking</p> <p>23 questions as if the differences between these two</p> <p>24 paragraphs is intentional. That's why I said</p>

<p style="text-align: right;">Page 58</p> <p>1 earlier I think you're reading too much into this.</p> <p>2 Because one says company documents and</p> <p>3 the other does not, does not mean that I didn't</p> <p>4 have a working knowledge of company documents.</p> <p>5 I've seen company documents long before I agreed</p> <p>6 to sign on to do these reports.</p> <p>7 I have seen ACOG committee opinions,</p> <p>8 position statements from different gynecological</p> <p>9 surgical societies. I've read the literature long</p> <p>10 before I agreed to do these reports.</p> <p>11 So, again I think we're getting into a</p> <p>12 lot of questions here that I think are reading too</p> <p>13 much into what my thought process is. There's</p> <p>14 nothing nefarious in section two of either of my</p> <p>15 reports.</p> <p>16 BY MS. GAYLE:</p> <p>17 Q. And, Doctor I don't mean for my question</p> <p>18 to sound nefarious to you.</p> <p>19 A. I understand.</p> <p>20 Q. As I said before, my job is to get to the</p> <p>21 basis of your opinions.</p> <p>22 A. I understand.</p> <p>23 Q. And so my question is simply, did you</p> <p>24 review company documents for your opinions contained in</p>	<p style="text-align: right;">Page 60</p> <p>1 course of serving as a treating physician in other</p> <p>2 cases. Those things have been reviewed in the past. I</p> <p>3 can't say for certain if I had any of those open on a</p> <p>4 separate screen as I was writing a report.</p> <p>5 Q. Thank you, Doctor. Now, let's just break</p> <p>6 that down a little bit.</p> <p>7 The ones that were in your head, you said</p> <p>8 that may have been from work that you did previously as</p> <p>9 a treating physician, correct?</p> <p>10 A. All right.</p> <p>11 Q. We're talking about internal company</p> <p>12 documents. Would those documents have been familiar to</p> <p>13 you through any of the expert work that you previously</p> <p>14 did for Butler Snow?</p> <p>15 MR. WALKER: Object to form.</p> <p>16 THE WITNESS: I don't recall. I don't</p> <p>17 recall when I looked at company documents. Maybe</p> <p>18 if you define company documents for me and tell me</p> <p>19 what you're talking about that may help.</p> <p>20 Do you consider a surgeon's resource</p> <p>21 monograph as a company document?</p> <p>22 BY MS. GAYLE:</p> <p>23 Q. Doctor, I'm letting you use the company</p> <p>24 documents as you would refer to them because it's your</p>
<p style="text-align: right;">Page 59</p> <p>1 Exhibit 7?</p> <p>2 MR. WALKER: Object to form.</p> <p>3 THE WITNESS: I have reviewed company</p> <p>4 documents to formulate opinions for both of my</p> <p>5 reports.</p> <p>6 BY MS. GAYLE:</p> <p>7 Q. Thank you, Doctor. So the fact that the</p> <p>8 phrase company documents in one report and omitted in</p> <p>9 the other is simply inconsequential to you?</p> <p>10 MR. WALKER: Object to form.</p> <p>11 THE WITNESS: Let's see. You know, I</p> <p>12 don't know if I specifically went back and looked</p> <p>13 at a company document while I was writing the TVT</p> <p>14 report.</p> <p>15 BY MS. GAYLE:</p> <p>16 Q. Okay. Thank you, Doctor.</p> <p>17 A. Okay. What I will say again, before I</p> <p>18 did either of these reports, a basic working knowledge</p> <p>19 of company documents is something that was already in</p> <p>20 my head along with research, along with committee</p> <p>21 opinions.</p> <p>22 So again, that was all information that</p> <p>23 had been reviewed by me at some point in time, whether</p> <p>24 it was during my residency or fellowship or during my</p>	<p style="text-align: right;">Page 61</p> <p>1 phrase in this --</p> <p>2 A. I've seen multiple company documents</p> <p>3 ranging from surgeon's resource monographs to internal</p> <p>4 company documents.</p> <p>5 Q. Okay. And, Doctor, if we would -- if you</p> <p>6 would turn back to the first page of both of your</p> <p>7 reports.</p> <p>8 As I indicated earlier, there's just a</p> <p>9 little bit of duplicity there and we can agree that</p> <p>10 section one of your credentials and qualifications in</p> <p>11 both Exhibit 4 and Exhibit 7 is the same. Would you</p> <p>12 say that, Doctor?</p> <p>13 A. They should be the same, yes.</p> <p>14 Q. With the exception of on page four of</p> <p>15 those -- of your report, Doctor, towards the end you</p> <p>16 would see that I have highlighted the words Prolift,</p> <p>17 Prolift+M and Gynemesh in Exhibit 4 whereas you have</p> <p>18 the other products TVT, TVT-Exact and TVT-O in</p> <p>19 Exhibit 7, correct, Doctor?</p> <p>20 A. Correct.</p> <p>21 Q. And, Doctor, turning to exhibit or,</p> <p>22 excuse me, section number three in your report, your</p> <p>23 fees. Those two sections would be identical; is that</p> <p>24 correct?</p>

<p style="text-align: right;">Page 62</p> <p>1 A. They should be.</p> <p>2 Q. And, Doctor, we've already discussed your</p> <p>3 fee rate which is exactly what is stated here. That's</p> <p>4 not changed, correct?</p> <p>5 A. Correct.</p> <p>6 Q. Turning to page six, Doctor, of your</p> <p>7 report, Exhibit 7, and then turn to page six of</p> <p>8 Exhibit 4, Doctor.</p> <p>9 With respect to the section number four,</p> <p>10 your expert opinion on your TVT report, the section</p> <p>11 appears the same up to letter A except for the phrase</p> <p>12 in Exhibit 7 as it pertains to stress urinary</p> <p>13 incontinence.</p> <p>14 Do you see those words on page six?</p> <p>15 A. I do.</p> <p>16 Q. And that differs to your Exhibit 4 which</p> <p>17 says as it pertains to prolapse treatment; is that</p> <p>18 right?</p> <p>19 A. That's right.</p> <p>20 Q. Doctor, if you would turn to page 10 and</p> <p>21 11 of your Exhibit Number 7, and then place Exhibit 4</p> <p>22 in front of you and turn to pages nine and ten.</p> <p>23 A. Uh-huh.</p> <p>24 Q. Again, Doctor, for your convenience I</p>	<p style="text-align: right;">Page 64</p> <p>1 paragraph. That would be the only difference, can we</p> <p>2 agree to that, Doctor?</p> <p>3 A. Correct.</p> <p>4 Q. And, Doctor, you just spoke a moment ago</p> <p>5 sort of about your drafting process and you said, you</p> <p>6 know, you may have had different screens open when you</p> <p>7 sort of sat down pen to paper or, you know, fingers to</p> <p>8 keyboard, if you will, drafting these.</p> <p>9 Did you sort of cut and paste like your</p> <p>10 bio section from one report to another? Did you use</p> <p>11 that as template? Can you sort of explain to me what</p> <p>12 your process was for drafting your reports?</p> <p>13 A. If there was something that was similar</p> <p>14 that was not specific to TVT or Prolift such as my</p> <p>15 rates and qualifications, then that may have been</p> <p>16 copied and pasted based on to a secondary report.</p> <p>17 Otherwise expert opinion sections mostly would have</p> <p>18 been dictated rather than typed through a program on my</p> <p>19 computer at home, and gone back in and reviewed and</p> <p>20 revised as needed.</p> <p>21 Q. And, Doctor, what program would that have</p> <p>22 been that you used at home?</p> <p>23 A. Oh, it's just a voice to text program</p> <p>24 that's part of Microsoft Word.</p>
<p style="text-align: right;">Page 63</p> <p>1 have highlighted the language that begins with the</p> <p>2 words a study by Sarma. Do you see that, Doctor?</p> <p>3 MR. WALKER: What page are you on?</p> <p>4 MS. GAYLE: On page ten of Exhibit 7.</p> <p>5 THE WITNESS: Yes.</p> <p>6 BY MS. GAYLE:</p> <p>7 Q. And going down all the way through the</p> <p>8 next page, Doctor, through the end of this section just</p> <p>9 above Section C, the last paragraph is while pessaries.</p> <p>10 Do you see that, Doctor?</p> <p>11 A. Pessary, yes.</p> <p>12 Q. And you see that I've highlighted and</p> <p>13 circled in red the words incontinence and prolapse?</p> <p>14 A. Correct.</p> <p>15 Q. And if you would look at your Exhibit</p> <p>16 Number 4 page number nine, again it's Exhibit 4, page</p> <p>17 nine. You would see that the words a study by Sarma is</p> <p>18 also found there?</p> <p>19 A. Correct.</p> <p>20 Q. And it goes all the way through again to</p> <p>21 the last paragraph of that section B?</p> <p>22 A. Yes.</p> <p>23 Q. Starting with while pessaries, and I've</p> <p>24 circled the words prolapse there in that last</p>	<p style="text-align: right;">Page 65</p> <p>1 Q. And, Doctor, they have changed the rules</p> <p>2 in Rule 26 recently, which I'm just letting counsel</p> <p>3 know that we can't get to your drafts but we can ask</p> <p>4 you, Doctor, when you were drafting those, did you from</p> <p>5 time to time send those to Butler Snow, ask them to</p> <p>6 look over it and maybe make any suggestions, and I</p> <p>7 don't want to get into the substance of any suggestions</p> <p>8 they would have made, but just did you send it to them</p> <p>9 for, you know, in the drafting process?</p> <p>10 A. They would have gotten a draft after I</p> <p>11 finished a complete report to review prior to</p> <p>12 signature.</p> <p>13 Q. And that would have been for both reports</p> <p>14 at Exhibit 4 and Exhibit 7, correct?</p> <p>15 A. That's correct.</p> <p>16 MS. GAYLE: How long have we been going?</p> <p>17 THE COURT REPORTER: One hour and nine</p> <p>18 minutes.</p> <p>19 MS. GAYLE: Okay. Let's take a quick</p> <p>20 break.</p> <p>21 (Recess taken.)</p> <p>22 BY MS. GAYLE:</p> <p>23 Q. So, Doctor, turning towards your reliance</p> <p>24 list which were, as we discussed previously, your</p>

<p style="text-align: right;">Page 66</p> <p>1 Exhibit 5 and your Exhibit 6, as you said that those  2 were a mix of materials that had been given to you as  3 well as things that you've cited, things that you  4 researched, correct?  5 A. Correct.  6 Q. And, Doctor, in your binders, are those  7 the materials that you simply cited in your report or  8 are those a mix of materials as well?  9 A. They will be a mix of materials, I think.  10 Q. Okay. Meaning partly from the defense,  11 partly that you asked them to put together?  12 A. You know, I can take the time to go  13 through these and compare and make sure.  14 MR. WALKER: I can clear this up.  15 THE WITNESS: Maybe he can help.  16 MR. WALKER: We put this together for him  17 to assist in the deposition today. So he had his  18 materials handy to reference as you ask questions,  19 and everything behind his report in these binders  20 should only be medical literature or other  21 documents that he specifically cites in the body  22 of his report.  23 MS. GAYLE: Okay. Thank you.  24 BY MS. GAYLE:</p>	<p style="text-align: right;">Page 68</p> <p>1 Q. And I'm not inferring that you do,  2 Doctor. You said you that had performed a systematic  3 review in the last couple of months.  4 And my question was, in performing that  5 systematic review if you would have found something  6 relevant to your opinions that you thought was relevant  7 in the last say year or so, you would have likely  8 picked that up, correct?  9 A. Unless we thought that was redundant from  10 another study.  11 Q. And can you think of anything right now  12 that you think would have been redundant that you  13 excluded?  14 A. There's a lot of redundancy. There's a  15 lost of randomized controlled trials out there and a  16 lot of newer trials that have come out just in the last  17 six months that show redundancy, that show long term  18 safety and efficacy of the products.  19 Q. Do you know off the top of your head  20 which trials you're referencing?  21 A. Are we talking specifically about the  22 slings right now or are we talking about Prolifts?  23 Q. I'm just trying to get to -- you just  24 said there's a lot of redundancy.</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. In putting together your materials that  2 you reviewed, Doctor, did you do an independent  3 systematic review and decide on which of the articles  4 you wanted to list in rendering your opinions?  5 A. Yes, I did.  6 Q. And can you explain that systematic  7 review process, Doctor?  8 A. Well, I'm looking through Pub Med. I'm  9 looking at trying to filter through and pick out  10 Cochrane database reviews and looking at trying to find  11 long term randomized controlled trials.  12 Q. Do you know the last time you performed  13 that independent systematic review?  14 A. It would have been within the last few  15 months as I was writing the reports.  16 Q. So in other words, Doctor, if something  17 was perhaps published in February of 2017 that you  18 found that was important, you would have picked that up  19 in your review; is that correct?  20 MR. WALKER: Object to form.  21 THE WITNESS: Well, I don't know that I  22 have everything that's been published in the last  23 20 years on midurethral slings.  24 BY MS. GAYLE:</p>	<p style="text-align: right;">Page 69</p> <p>1 A. Yes. So, well, for instance, in the  2 slings there have been two publications this year  3 looking at 17 year data on midurethral slings.  4 So when I say redundancy, I don't  5 necessarily mean that the rates of efficacy or rates of  6 complications are identical. What I mean to say is  7 that 17 year data from a couple of studies from this  8 year show very high long term efficacy rates just like  9 some of the 13 and 17 year studies that were referenced  10 from previous years.  11 Q. Doctor, in receiving the medical articles  12 that defense counsel provided you, your reliance list  13 also lists expert reports that we've spoken about  14 earlier and I forgot to ask you, did you receive those  15 expert reports from Butler Snow?  16 A. Yes.  17 Q. Did you include anything that you might  18 have had, you know, lying around in your own personal  19 collection as far as expert reports?  20 A. No.  21 Q. Did you -- strike that. Doctor, in your  22 reliance list materials you list one report by a  23 defense expert, doctor, and I might pronounce his name  24 incorrectly, Toglia, T-O-G-L-I-A?</p>



<p style="text-align: right;">Page 70</p> <p>1 A. Marc Toglia.</p> <p>2 Q. Okay. Do you know him, Doctor?</p> <p>3 A. Yes.</p> <p>4 Q. Personally?</p> <p>5 A. Yes.</p> <p>6 Q. How long have you known him?</p> <p>7 A. Since -- I guess since I became a member</p> <p>8 of the Society of Gynecologic Surgeons.</p> <p>9 Q. What was that date, Doctor?</p> <p>10 A. Give me one second.</p> <p>11 Q. Approximately is fine.</p> <p>12 A. No, I want to give you --</p> <p>13 Q. Will it be on your CV?</p> <p>14 A. It will be on my CV.</p> <p>15 Q. Okay. Thank you, Doctor. And other than</p> <p>16 Toglia's report --</p> <p>17 A. That would have been 2012.</p> <p>18 Q. Okay. Thank you, Doctor. Other than Dr.</p> <p>19 Toglia's report, do you recall any other reports that</p> <p>20 would have been defense experts that you would have</p> <p>21 reviewed?</p> <p>22 A. No. No, I don't recall reviewing any</p> <p>23 other defense expert report.</p> <p>24 Q. So, Doctor, we've talked about the total</p>	<p style="text-align: right;">Page 72</p> <p>1 Q. Okay. Do you know Dr. Richard Ellkerman</p> <p>2 E-l-l-e-r-m-a-n?</p> <p>3 A. I've heard the name. I don't know who he</p> <p>4 is. I don't know him personally.</p> <p>5 Q. You cited an Ellkerman study in your</p> <p>6 report.</p> <p>7 A. Which report?</p> <p>8 Q. Good question, Doctor. I'll withdraw the</p> <p>9 question, Doctor, because I don't know which report but</p> <p>10 you don't know Dr. Ellkerman personally, correct?</p> <p>11 A. No.</p> <p>12 Q. And because you don't know him personally</p> <p>13 you would not know whether or not he's a defense expert</p> <p>14 for the defendants in this multi-district litigation,</p> <p>15 would you?</p> <p>16 A. I don't know anything about him other</p> <p>17 than his research.</p> <p>18 (Exhibit 10 - Richard Ellkerman's reliance list.)</p> <p>19 BY MS. GAYLE:</p> <p>20 Q. Doctor, I represent to you that he is an</p> <p>21 expert that's been named in Wave 8 and he's tendered an</p> <p>22 expert report, and I'm handing you what's been marked</p> <p>23 as Exhibit 10 which is entitled Richard Ellkerman,</p> <p>24 General Reliance List in Addition to Materials</p>
<p style="text-align: right;">Page 71</p> <p>1 basket of all the materials that you've reviewed into</p> <p>2 putting -- into forming your opinions in both reports,</p> <p>3 would that be fair?</p> <p>4 A. I mean we have not specifically discussed</p> <p>5 each one of the trials but, yes, in terms of what I</p> <p>6 utilized to form my opinions it was a combination of my</p> <p>7 background, training, experience as a gynecologic</p> <p>8 surgeon, company documents, multiple randomized</p> <p>9 controlled clinical trials, Cochrane databases,</p> <p>10 studies, committee opinions, professional organization</p> <p>11 opinions. Its all been used.</p> <p>12 Q. Thank you, Doctor. And one last question</p> <p>13 on that subject. I did ask you if defendants or Butler</p> <p>14 Snow had given you any sort of expert reports.</p> <p>15 Did any of your, say, doctors or friends</p> <p>16 that you know in the medical community, did they send</p> <p>17 you any sort of expert reports through your drafting</p> <p>18 process?</p> <p>19 A. No.</p> <p>20 Q. So in other words, Dr. Toglia, for</p> <p>21 instance would not have emailed you and said hey,</p> <p>22 here's, you know, my expert report that I issued in a</p> <p>23 certain Wave, look at that, right?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 73</p> <p>1 referenced in Report.</p> <p>2 Doctor, if you'd take your Exhibit 5 and</p> <p>3 your Exhibit 6 and compare them to Dr. Ellkerman's</p> <p>4 they're almost identical in formatting, font, exactly</p> <p>5 the same, including typographical errors.</p> <p>6 I believe counsel said earlier that they</p> <p>7 prepared the reliance list for you. So since you</p> <p>8 didn't prepare it, would that be a possible explanation</p> <p>9 on why your report, your reliance list materials would</p> <p>10 be identical to Dr. Ellkerman's?</p> <p>11 MR. WALKER: Objection to form.</p> <p>12 THE WITNESS: Again, I don't know about</p> <p>13 Ellkerman's reliance list. I didn't put the</p> <p>14 reliance list together. I did my own reports and</p> <p>15 so I can't really speak to his reliance list.</p> <p>16 BY MS. GAYLE:</p> <p>17 Q. So any type -- but you didn't copy his</p> <p>18 reliance list, is that what you're saying?</p> <p>19 A. No, I didn't copy his reliance list.</p> <p>20 MR. WALKER: Object to form.</p> <p>21 BY MS. GAYLE:</p> <p>22 Q. So you didn't type this reliance at</p> <p>23 Exhibit 5 or 6 either, did you?</p> <p>24 MR. WALKER: Object to form. He's</p>



<p style="text-align: right;">Page 74</p> <p>1 already testified.</p> <p>2 THE WITNESS: No, I think we made that</p> <p>3 clear earlier.</p> <p>4 BY MS. GAYLE:</p> <p>5 Q. Okay. Great. Butler Snow put that</p> <p>6 together, right?</p> <p>7 MR. WALKER: Object to form.</p> <p>8 THE WITNESS: That's correct.</p> <p>9 (Exhibit 11 - Dr. Ahmet Bedestani general</p> <p>10 reliance list.)</p> <p>11 BY MS. GAYLE:</p> <p>12 Q. Doctor, same thing with Dr. Bedestani,</p> <p>13 B-e-d-e-s-t-a-n-i, Ahmet first name, A-h-m-e-t, General</p> <p>14 Reliance List in Addition to Materials Referenced in</p> <p>15 Report, I have marked that as exhibit number 11.</p> <p>16 Again, Doctor, do you know that</p> <p>17 particular doctor?</p> <p>18 A. No.</p> <p>19 Q. And you would not know whether or not</p> <p>20 that doctor was an expert designated in this</p> <p>21 litigation?</p> <p>22 A. No.</p> <p>23 Q. And again, any similarities between Dr.</p> <p>24 Bedestani's reliance list, Exhibit 11, and yours at</p>	<p style="text-align: right;">Page 76</p> <p>1 reliance list Butler Snow this week had provided</p> <p>2 another reliance list for you that was a supplemental</p> <p>3 reliance list.</p> <p>4 MS. GAYLE: My apologies, Madam Court</p> <p>5 Reporter. I've marked it as Exhibit 21. So</p> <p>6 towards the end.</p> <p>7 (Exhibit 21 - Bryce Bowling Supplemental General</p> <p>8 Materials List in Addition to Materials</p> <p>9 Referenced in Report.)</p> <p>10 BY MS. GAYLE:</p> <p>11 Q. Doctor, I'm handing you that reliance</p> <p>12 list and that's a supplemental. Do you know what the</p> <p>13 changes were in that reliance list as compared to</p> <p>14 Exhibit 5 and 6?</p> <p>15 A. I do not.</p> <p>16 Q. Did you ask Butler Snow to include any</p> <p>17 material in your supplemental reliance list in forming</p> <p>18 this?</p> <p>19 A. You know, let me just go back and clarify</p> <p>20 one more time. The reliance list has been put together</p> <p>21 by Butler Snow. It is a culmination of materials that</p> <p>22 they provided to me that I requested and that I</p> <p>23 researched on my own and cited in my report.</p> <p>24 I did not type the reliance list. I'm</p>
<p style="text-align: right;">Page 75</p> <p>1 Exhibit 5 and 6 would also be something that you would</p> <p>2 not be familiar with?</p> <p>3 MR. WALKER: Object to form.</p> <p>4 THE WITNESS: You will have to speak with</p> <p>5 Butler Snow about that. I don't get involved in</p> <p>6 other people's reliance list.</p> <p>7 BY MS. GAYLE:</p> <p>8 Q. Okay. And certainly you didn't cut and</p> <p>9 paste from this reliance list, correct?</p> <p>10 MR. WALKER: Object to form. He's made</p> <p>11 it crystal clear he did not put together the</p> <p>12 reliance list.</p> <p>13 MS. GAYLE: Thank you, counsel. I just</p> <p>14 want to make sure that there's no -- you know, he</p> <p>15 did say earlier that he put some, maybe some</p> <p>16 materials.</p> <p>17 So as long as you all put this together,</p> <p>18 that's all I'm trying to get at.</p> <p>19 MR. WALKER: That's what has been</p> <p>20 represented numerous times now on the record.</p> <p>21 MS. GAYLE: Thank you.</p> <p>22 (Exhibit 21 - Supplemental reliance list.)</p> <p>23 BY MS. GAYLE:</p> <p>24 Q. Doctor, while we're talking about the</p>	<p style="text-align: right;">Page 77</p> <p>1 not aware of any supplements to the reliance list. The</p> <p>2 only interaction that I've had with that reliance list</p> <p>3 is seen it at the end of my report.</p> <p>4 Q. Thank you, Doctor. Doctor, in your</p> <p>5 reliance list you list the depositions of two company</p> <p>6 witnesses and that would be for Exhibit 5, Exhibit 6</p> <p>7 and Exhibit 21.</p> <p>8 You list Piet Hinoul and Martin Weisberg.</p> <p>9 Do you know Piet Hinoul?</p> <p>10 A. I don't know him personally. I know who</p> <p>11 is he.</p> <p>12 Q. Okay. Can you tell me just for the</p> <p>13 record, Doctor, who he is?</p> <p>14 A. Well I don't know his exact title. I</p> <p>15 think he's in the medical affairs, maybe medical</p> <p>16 director at Ethicon. He's a urogynecologist.</p> <p>17 Q. Okay. And you also listed the deposition</p> <p>18 of Martin Weisberg.</p> <p>19 A. Uh-huh.</p> <p>20 Q. Do you know who Martin Weisberg is?</p> <p>21 A. (Witness nods head.)</p> <p>22 Q. Who is he, Doctor?</p> <p>23 A. He also works at Ethicon. He's also a</p> <p>24 medical doctor and works, I think, in the medical</p>

<p style="text-align: right;">Page 78</p> <p>1 affairs portion of Ethicon.</p> <p>2 Q. Okay. And you listed one depo for each</p> <p>3 of those particular individuals?</p> <p>4 A. Uh-huh.</p> <p>5 Q. Was there anything specific in either</p> <p>6 depo that stood out to you, Doctor?</p> <p>7 A. No.</p> <p>8 Q. Doctor, turning to your role in this</p> <p>9 litigation, you do not have an engineering degree, do</p> <p>10 you?</p> <p>11 A. I have a medical degree.</p> <p>12 Q. Okay. You're not holding yourself out as</p> <p>13 an expert in the field of engineering, are you, doctor?</p> <p>14 A. Well, define expert in engineering.</p> <p>15 Q. So, Doctor, just as you're an expert in</p> <p>16 medical, you have a degree. An engineer would be an</p> <p>17 expert in engineering, would hold an engineering degree</p> <p>18 and be offering opinions in the field of engineering.</p> <p>19 I didn't see that on your CV.</p> <p>20 A. Again, I think if you want to be specific</p> <p>21 about what the word expert means. If you mean do I</p> <p>22 have a degree in engineering, no, I do not.</p> <p>23 Do I have knowledge as a surgeon and as a</p> <p>24 medical doctor about design issues, about how mesh</p>	<p style="text-align: right;">Page 80</p> <p>1 women.</p> <p>2 Q. Do you remember what they were?</p> <p>3 A. Some of them actually didn't even have</p> <p>4 names. We were -- and some of them weren't finished</p> <p>5 products. A lot of this was ideas and design.</p> <p>6 Q. Were you paid for your work to sit on</p> <p>7 that committee, Doctor?</p> <p>8 A. I was.</p> <p>9 Q. Was that the only work that you did for</p> <p>10 AMS?</p> <p>11 A. Yes, just design.</p> <p>12 Q. And, Doctor, we talked about AMS and we</p> <p>13 talked about some of your work with Butler Snow in</p> <p>14 regard to this litigation.</p> <p>15 Have you worked for any other defendant</p> <p>16 in the transvaginal mesh litigation?</p> <p>17 A. No.</p> <p>18 Q. For instance, you've not worked for</p> <p>19 Boston Scientific?</p> <p>20 A. No.</p> <p>21 Q. Coloplast?</p> <p>22 A. Well, okay.</p> <p>23 MR. WALKER: Can I clarify one thing?</p> <p>24 Are you asking in a litigation capacity?</p>
<p style="text-align: right;">Page 79</p> <p>1 incorporates into human tissue and about the</p> <p>2 complications that can go along with certain types of</p> <p>3 designs, then, yes, I would consider myself an expert.</p> <p>4 Q. So you would consider yourself an expert</p> <p>5 on the design of transvaginal mesh products?</p> <p>6 A. I think, yes, as a surgeon who has</p> <p>7 implanted thousands of pieces of mesh. I also sat on</p> <p>8 committees where we have looked at mesh design and mesh</p> <p>9 innovation, looking at complications, looking at the</p> <p>10 design and shape of meshes, composition of meshes.</p> <p>11 I've spent several years doing that on committees.</p> <p>12 Q. Can you give me an example of those</p> <p>13 committees that you would have sat on, Doctor?</p> <p>14 A. Sure. I sat on a AMS, American Medical</p> <p>15 Systems committee for three years.</p> <p>16 Q. Do you know when that was, Doctor?</p> <p>17 A. It's in my CV.</p> <p>18 Q. Okay.</p> <p>19 A. I'll find the dates for you.</p> <p>20 Q. What device was that that you were</p> <p>21 designing?</p> <p>22 A. That would have been 2013, '14 and '15</p> <p>23 and those were multiple devices that we were looking at</p> <p>24 for possibilities in treating pelvic organ prolapse in</p>	<p style="text-align: right;">Page 81</p> <p>1 MS. GAYLE: In a litigation capacity,</p> <p>2 yes.</p> <p>3 THE WITNESS: Okay. So in a litigation</p> <p>4 capacity, no, I have not worked for any of the --</p> <p>5 well, you ask your questions. Boston Scientific,</p> <p>6 no, I've not worked for Boston Scientific.</p> <p>7 BY MS. GAYLE:</p> <p>8 Q. In a non-litigation capacity, Doctor,</p> <p>9 have you worked -- what other pharmaceutical medical</p> <p>10 device companies have you worked for or with?</p> <p>11 A. I worked from 2011 to 2013 with a company</p> <p>12 known as Warner Chilcott who at the time was in charge</p> <p>13 of certain medications used for overactive bladder.</p> <p>14 Outside of that and American Medical</p> <p>15 Systems and the current litigation ongoing, I've not</p> <p>16 worked for any medical device corporations.</p> <p>17 Q. Doctor, you've never designed a medical</p> <p>18 device by yourself, would that be correct?</p> <p>19 A. I have not patented a medical device, but</p> <p>20 yes, I have designed medical devices.</p> <p>21 Q. So you have no patents on any medical</p> <p>22 device that you may have designed?</p> <p>23 A. Unfortunately, no.</p> <p>24 Q. And when you say that you did design a</p>

<p style="text-align: right;">Page 82</p> <p>1 medical device, without getting into the specifics, as</p> <p>2 you said you don't have a patent, would that be a</p> <p>3 transvaginal mesh device?</p> <p>4 A. No.</p> <p>5 Q. Would it be a mesh or a device used for</p> <p>6 any of the conditions that we're discussing?</p> <p>7 A. It is a device used in the assessment and</p> <p>8 treatment of women with urinary incontinence.</p> <p>9 Q. Is there any reason that you haven't</p> <p>10 sought a patent on that, Doctor?</p> <p>11 A. Time constraints.</p> <p>12 Q. Doctor, you don't have a degree in</p> <p>13 biomechanics, do you?</p> <p>14 A. I do not have a degree in biomechanics.</p> <p>15 I have a degree in biology.</p> <p>16 Q. And I'm sorry, I just sort of have to</p> <p>17 tick through this list for clarification.</p> <p>18 A. Sure.</p> <p>19 Q. And, Doctor, you don't have a degree in</p> <p>20 pathology, correct?</p> <p>21 A. I do not have a degree in pathology, but</p> <p>22 I have reviewed thousands upon thousands of pathology</p> <p>23 reports and I have explanted several hundred pieces of</p> <p>24 mesh and seen the reactions and surrounding tissues,</p>	<p style="text-align: right;">Page 84</p> <p>1 THE WITNESS: Not that I'm aware.</p> <p>2 BY MS. GAYLE:</p> <p>3 Q. You don't hold a biomedical engineer</p> <p>4 degree, do you?</p> <p>5 A. I do not have a degree in biomedical</p> <p>6 engineering. I have a medical degree and I have a</p> <p>7 biology degree.</p> <p>8 Q. Sorry, Doctor. Like I said, I just have</p> <p>9 to tick through my list.</p> <p>10 A. That's fine.</p> <p>11 Q. You don't have a chemical engineering,</p> <p>12 degree, correct?</p> <p>13 A. I do not have a degree in chemical</p> <p>14 engineering.</p> <p>15 Q. You do not have polymer chemistry degree,</p> <p>16 correct?</p> <p>17 A. I don't have a polymer chemistry degree,</p> <p>18 but in terms of implanting and knowing how these</p> <p>19 materials interact in the human body in terms of their</p> <p>20 biologic component, in terms of the way that the</p> <p>21 synthetic meshes interact with the human body, I would</p> <p>22 consider myself an expert.</p> <p>23 Q. Doctor, have you ever done any bench</p> <p>24 research on polypropylene mesh?</p>
<p style="text-align: right;">Page 83</p> <p>1 but I do not have a degree in pathology.</p> <p>2 Q. And, Doctor, do you know if you're</p> <p>3 designated as pathologist in Wave 8?</p> <p>4 A. I am not, to the best of my knowledge.</p> <p>5 Q. And you're not designated as a</p> <p>6 biomechanics expert either in Wave 8?</p> <p>7 A. I don't believe that I am.</p> <p>8 Q. Doctor, are you holding yourself out as</p> <p>9 an expert in the Food and Drug Administration, medical</p> <p>10 device labeling and requirements?</p> <p>11 A. Well, I think from the physician, from</p> <p>12 the medical side of things, knowing how drugs and being</p> <p>13 on the side of studying drugs and devices in the past,</p> <p>14 knowing how those procedures are studied, how they're</p> <p>15 cleared and how they work in the current medical-legal</p> <p>16 environment, I'd say I'm very well versed in that.</p> <p>17 I do not sit on an FDA board. I don't</p> <p>18 make rules for how the FDA clears medical devices, but</p> <p>19 I have ample experience in how devices make their way</p> <p>20 through the system.</p> <p>21 Q. And you've not been designated as an</p> <p>22 expert in Food and Drug Administration in this Wave or</p> <p>23 in the Election Wave, correct?</p> <p>24 MR. WALKER: Object to the form.</p>	<p style="text-align: right;">Page 85</p> <p>1 A. Bench. Define bench research for me.</p> <p>2 Have I taken a piece of mesh into the lab and stretched</p> <p>3 it to see how long it takes to break?</p> <p>4 Personally, I have not done that. I do</p> <p>5 have several publications in -- with mesh related</p> <p>6 products though.</p> <p>7 Q. Are those relating to bench research?</p> <p>8 A. Define bench research.</p> <p>9 Q. As you understand it, Doctor.</p> <p>10 A. Well, I'm not --</p> <p>11 Q. You just said you've not taken it into</p> <p>12 the lab so --</p> <p>13 A. Yeah, I've not taken -- again, I'll</p> <p>14 clarify. I have not taken a piece of mesh into the lab</p> <p>15 and stretched it to find out when it breaks. If that's</p> <p>16 the definition of bench research then, no, I have not</p> <p>17 done that.</p> <p>18 Q. And similarly, Doctor, have you done any</p> <p>19 lab research on polypropylene?</p> <p>20 A. What kind of lab research?</p> <p>21 Q. Well, anything regarding work in the</p> <p>22 laboratory on polypropylene in a laboratory setting?</p> <p>23 A. You know, we have done several cadaver</p> <p>24 dissection labs where we've utilized mesh. I've taught</p>

<p style="text-align: right;">Page 86</p> <p>1 not only medical students and residents but other  2 faculty members both at the University of Alabama  3 Birmingham and here at the University of Tennessee  4 Medical Center, cadaver labs where mesh and its  5 interaction with the tissue was heavily discussed.  6 Q. Any other types of labs, Doctor?  7 A. Outside of the cadaver labs we have done  8 cystoscopic evaluations in laboratory settings of  9 complications from mesh as well as suture  10 complications.  11 Outside of those, probably the only  12 laboratory settings that we've done related to mesh.  13 Q. Thank you, Doctor. Have you done any  14 type of pathological analysis on the explant of  15 polypropylene?  16 A. Define for me analysis.  17 Q. Where you look at it under the microscope  18 and publish your opinions?  19 A. Look at it under the microscope? Yes,  20 absolutely. Publish opinions, I have not published an  21 opinion based on the microscopic analysis of mesh but I  22 have reviewed pathology reports. I have sat with  23 pathologists and looked at explant materials.  24 Q. Do you do that with every explant that</p>	<p style="text-align: right;">Page 88</p> <p>1 A. No. My publications in mesh are listed  2 here on my CV, including removals of mesh and repair of  3 complications related to implants.  4 Q. Doctor, I think we talked about this a  5 little bit earlier. On your invoices with Exhibit 3,  6 the earliest invoice that you had was in March.  7 Was that the first time that you were  8 contacted about being a general expert in this  9 particular Wave, that you recall?  10 A. I think when I was first contacted I  11 wasn't contacted to be a general expert. I think  12 initially I was contacted to be a case specific expert.  13 Q. Would the March 2018 date be consistent  14 with when you first started your work as a general  15 expert?  16 A. If you'll give me one second.  17 Q. Certainly.  18 A. I will give you a date. It looks like I  19 was initially contacted around mid-February.  20 Q. Okay. Thank you, Doctor. And we've  21 talked about the invoices and so forth that you had.  22 Off the top of your head, Doctor, can you  23 break down how much time you spent preparing each of  24 the two separate reports?</p>
<p style="text-align: right;">Page 87</p> <p>1 you explant?  2 A. No.  3 Q. Doctor, you don't have a biomaterials  4 degree either, correct?  5 A. Again, I don't have a degree in  6 biomaterials, but I do consider myself an bit of an  7 expert when it comes to the way that materials interact  8 with human tissues.  9 Q. And the reason you consider yourself an  10 expert again, Doctor, is based on your work?  11 A. Based on 15 years of performing pelvic  12 organ prolapse procedures with and without mesh,  13 dealing with the complications that go along with not  14 only mesh implants but also permanent suture implants,  15 and seeing how those implants both mesh and non-mesh  16 interact with the human body.  17 Q. Doctor, you haven't published anything on  18 polypropylene mesh and degradation in the human body,  19 have you?  20 A. I have not published anything regarding  21 degradation.  22 Q. And you have not published anything  23 regarding polypropylene and a foreign body reaction,  24 have you?</p>	<p style="text-align: right;">Page 89</p> <p>1 A. Probably 30 to 40 hours on each report.  2 Q. Would that include your drafting process?  3 A. Correct.  4 (Exhibit 8 - Curriculum Vitae.)  5 (Exhibit 9 - Curriculum Vitae.)  6 BY MS. GAYLE:  7 Q. Doctor, I'm handing what's been marked as  8 your Exhibit 8 and your Exhibit 9. Those are your CVs  9 that were respectively supplied with your Exhibit 4,  10 your POP report and your Exhibit 7, your TVT report.  11 It appears that Exhibit 8 and 9 were  12 identical in all respects. Is that the case to the  13 best of your knowledge, doctor?  14 A. I can take the time to look through them  15 and see if they're identical. If you are representing  16 they are identical, I won't disagree with that.  17 Q. We can take a moment for you to look,  18 Doctor.  19 MS. GAYLE: Go off the record.  20 (Off record discussion.)  21 THE WITNESS: They appear to be the same.  22 (Exhibit 12 - Resume in 2012.)  23 BY MS. GAYLE:  24 Q. Thank you, Doctor. And I'm going to hand</p>

<p style="text-align: right;">Page 90</p> <p>1 you what has also been marked as Exhibit 12. Thank</p> <p>2 you, Doctor.</p> <p>3 And this appears to be an earlier</p> <p>4 iteration of your resume online, which I presume would</p> <p>5 have been superceded by your resume that you provided</p> <p>6 this month. I believe this one was online in 2012.</p> <p>7 A. Okay.</p> <p>8 Q. And we might look at those in just a</p> <p>9 little while, Doctor. I have just a few questions with</p> <p>10 regard to those.</p> <p>11 And then, of course, as you had prepared</p> <p>12 earlier and given to us a resume that we are going to</p> <p>13 mark as Exhibit 12-A, and that would be the one that</p> <p>14 you brought with you today.</p> <p>15 (Exhibit 12-A - Resume supplied on September</p> <p>16 28/2018.)</p> <p>17 BY MS. GAYLE:</p> <p>18 Q. Doctor, in your previous testimony you</p> <p>19 have testified that you haven't authored anything</p> <p>20 looking at long term treatments for pelvic organ</p> <p>21 prolapse kits. I didn't see anything on your current</p> <p>22 resume. Is that still the case?</p> <p>23 A. I've not authored anything. I have been</p> <p>24 involved in many of the trials looking at the long term</p>	<p style="text-align: right;">Page 92</p> <p>1 -- two of the three appear to be sling related.</p> <p>2 One is just a removal of mesh, but it</p> <p>3 does not say what the product was, so I don't know if</p> <p>4 that was a prolapse mesh or if that was a sling mesh.</p> <p>5 Q. Okay. Thank you, Doctor. Of the two of</p> <p>6 the three that are slings, do you know what slings</p> <p>7 those were?</p> <p>8 A. I do not. We did not list corporation</p> <p>9 information in the studies.</p> <p>10 Q. Was there a particular reason why you</p> <p>11 didn't list the corporation information?</p> <p>12 A. Because the corporations don't really</p> <p>13 matter. The use of polypropylene mesh and the</p> <p>14 complications that go along with them can stretch from</p> <p>15 every product manufacturer out there. So the</p> <p>16 corporation was not important in the study.</p> <p>17 Q. And, Doctor, I couldn't find anything</p> <p>18 that you've written on the Burch procedure. Have you</p> <p>19 written on the Burch procedure?</p> <p>20 A. I have lectured on the Burch procedure.</p> <p>21 I have not written. I'm not an author on any Burch</p> <p>22 papers.</p> <p>23 Q. And, Doctor, just to make things a little</p> <p>24 bit quicker that's all I'm trying to get at is whether</p>
<p style="text-align: right;">Page 91</p> <p>1 safety and efficacy of prolapse kits.</p> <p>2 Q. Were you a co-author on any of those?</p> <p>3 A. My name is not listed. I was the</p> <p>4 implanting surgeon in many of those. Those would have</p> <p>5 been during my fellowship years.</p> <p>6 Q. Does any particular one stick out in your</p> <p>7 mind, Doctor?</p> <p>8 A. No. Anything that would have been</p> <p>9 published out of the University of Alabama Birmingham,</p> <p>10 the Pelvic Floor Disorders Network or the Urinary</p> <p>11 Incontinence Treatment Network between the dates of</p> <p>12 2007 to 2010 I would have been involved in.</p> <p>13 Q. And, Doctor, I'm going to be asking you a</p> <p>14 series of questions with regard to the six products</p> <p>15 that you opinioned on. After I ask the first question</p> <p>16 you may anticipate for the following products if you</p> <p>17 wish.</p> <p>18 Do any of the publications listed in your</p> <p>19 current CV specifically address the Prolift product?</p> <p>20 A. Let's see. I think there are three. I</p> <p>21 have three mesh. Let's see if we have any others here.</p> <p>22 I think we have three publications dating</p> <p>23 from 2015 through 2017. Those do not have a name</p> <p>24 assigned to them in terms of what product, but they all</p>	<p style="text-align: right;">Page 93</p> <p>1 you've authored a peer-reviewed publication on these</p> <p>2 topics, okay?</p> <p>3 A. All right.</p> <p>4 Q. And have you written anything on</p> <p>5 biological tissue slings in a peer-reviewed journal?</p> <p>6 A. I have not authored anything in a</p> <p>7 peer-reviewed journal on biologic slings.</p> <p>8 Q. Doctor, earlier when we were talking</p> <p>9 about Prolift products, you had referenced some other</p> <p>10 techniques that were previously used.</p> <p>11 Would you agree that the Prolift was an</p> <p>12 alternative surgical procedure for the treatment of</p> <p>13 prolapse as compared to other techniques that are</p> <p>14 available to physicians?</p> <p>15 A. The Prolift was an alternative surgical</p> <p>16 procedure to address pelvic organ prolapse in women.</p> <p>17 Q. With regard to your current practice,</p> <p>18 your residency training was an obstetrics -- I think</p> <p>19 I'm going to need some water -- in gynecology, correct,</p> <p>20 OB/GYN?</p> <p>21 A. Unfortunately, yes.</p> <p>22 Q. You also completed a urogynecology</p> <p>23 fellowship program. As you said earlier, it was three</p> <p>24 years, correct?</p>



<p style="text-align: right;">Page 94</p> <p>1 A. Correct.</p> <p>2 Q. After your fellowship you limited your</p> <p>3 practice to female pelvic medicine and reconstructive</p> <p>4 surgery, correct?</p> <p>5 A. That's correct.</p> <p>6 Q. As we talked about before, you're board</p> <p>7 certified in OB/GYN as well as female pelvic medicine</p> <p>8 and reconstructive surgery, correct?</p> <p>9 A. Yes.</p> <p>10 Q. Would you agree that urogynecology is the</p> <p>11 same thing as pelvic medicine and reconstructive</p> <p>12 surgery?</p> <p>13 A. Yes.</p> <p>14 Q. As of April 2016 you testified you did</p> <p>15 not handle general obstetrics and gynecology in your</p> <p>16 practice, correct?</p> <p>17 A. That's correct.</p> <p>18 Q. Is that still the same, Doctor?</p> <p>19 A. Absolutely.</p> <p>20 Q. You don't handle any OB/GYN cases?</p> <p>21 A. Thankfully, no.</p> <p>22 Q. Not delivering babies today?</p> <p>23 A. No.</p> <p>24 Q. Let's see. We talked about when you</p>	<p style="text-align: right;">Page 96</p> <p>1 Q. Is that maybe the West Memphis</p> <p>2 Crittenton?</p> <p>3 A. No, that was different.</p> <p>4 Q. That's a different hospital?</p> <p>5 A. This was different. My training was at</p> <p>6 the Regional --- what was known formerly as the</p> <p>7 Regional Medical Center or The Med in Memphis.</p> <p>8 Q. Doctor, while we're talking about west</p> <p>9 Memphis, I noticed on one of your resumes that you had</p> <p>10 the facility there in West Memphis --</p> <p>11 A. Crittenton.</p> <p>12 Q. Crit tendon. It was on your 2012 resume</p> <p>13 but it wasn't -- I didn't see it on other resumes.</p> <p>14 A. Really?</p> <p>15 Q. That I noticed.</p> <p>16 A. It's on this most recent one.</p> <p>17 Q. Okay. It is on the most recent one?</p> <p>18 A. Yes. 2006 through 2007.</p> <p>19 Q. That's the facility that burned down.</p> <p>20 A. Did it?</p> <p>21 Q. Okay. You didn't know that it burned</p> <p>22 down?</p> <p>23 A. No. Completely unaware. Wow. Burned</p> <p>24 down.</p>
<p style="text-align: right;">Page 95</p> <p>1 first used your mesh, and in your fellowship training</p> <p>2 program you used mesh as part of the way that you</p> <p>3 surgically addressed pelvic organ prolapse or stress</p> <p>4 incontinence, correct?</p> <p>5 A. In some patients, yes.</p> <p>6 MR. WALKER: And just to clarify, I</p> <p>7 recall you asking him when you first used Prolift.</p> <p>8 I don't recall the same question about the slings.</p> <p>9 MS. GAYLE: Thank you.</p> <p>10 BY MS. GAYLE:</p> <p>11 Q. Doctor, for clarification, when did you</p> <p>12 first use slings?</p> <p>13 A. It would have been during my residency</p> <p>14 training between 2003 and 2007.</p> <p>15 MR. WALKER: We're talking about</p> <p>16 synthetic slings?</p> <p>17 THE WITNESS: Yes.</p> <p>18 MS. GAYLE: Yes.</p> <p>19 BY MS. GAYLE:</p> <p>20 Q. And where were you at that time, Doctor?</p> <p>21 A. I was at the University of Tennessee</p> <p>22 Medical Center in Memphis. I guess they called that</p> <p>23 the Regional Medical Center. I don't know. I think</p> <p>24 they've renamed it again. I don't know what it is.</p>	<p style="text-align: right;">Page 97</p> <p>1 Q. Okay. So let see, Doctor. As of</p> <p>2 April 2016 you had testified that you used every pelvic</p> <p>3 mesh product except the Mini-Slings. Is that still the</p> <p>4 case?</p> <p>5 A. Probably so. I think we've used</p> <p>6 throughout our -- my fellowship training and residency</p> <p>7 we probably used every type of pelvic mesh that was</p> <p>8 available on the market at that time.</p> <p>9 Q. Including the Mini-Slings?</p> <p>10 A. No, I've never touched a Mini-Sling.</p> <p>11 Q. And, Doctor, when you were just talking</p> <p>12 about the use of the synthetic slings as early as 2003,</p> <p>13 do you remember what product you initially used?</p> <p>14 A. I think throughout the residency training</p> <p>15 program they were the standard retropubic TVT sling.</p> <p>16 Q. Do you remember when you started using</p> <p>17 the TVT-Exact?</p> <p>18 A. It was after I came here. So it would</p> <p>19 have been somewhere in the range of 2010 to 2014-ish.</p> <p>20 Q. And the TVT-O, Doctor, do you know when</p> <p>21 you started using that?</p> <p>22 A. The TVT-O was utilized primarily during</p> <p>23 fellowship.</p> <p>24 Q. And, Doctor, you've testified elsewhere</p>



<p style="text-align: right;">Page 98</p> <p>1 that you really did not use the TVT-O in your practice</p> <p>2 as much particularly with regard to your other fellows.</p> <p>3 Is that still the case today?</p> <p>4 A. I'm sorry. We don't have fellows here.</p> <p>5 Q. I'm sorry. With persons that you're</p> <p>6 training throughout your teaching and training</p> <p>7 activities here at the university you said that you</p> <p>8 don't use the TVT-O?</p> <p>9 A. We do occasionally use TVT-Os here. We</p> <p>10 are majority retropubic, but we do use transobturator</p> <p>11 slings from time to time. They're not my sling of</p> <p>12 choice in the majority of patients, however.</p> <p>13 Q. Thank you. I think that was the phrase</p> <p>14 that you had said and testified to previously.</p> <p>15 TVT-O was not your sling of choice in</p> <p>16 these training pursuits, primarily because you had</p> <p>17 testified that there were complications that I believe</p> <p>18 you said an aggressive or overstimulated, other person</p> <p>19 that you were training could have punctured something</p> <p>20 or caused -- overaggressive student perhaps?</p> <p>21 MR. WALKER: Object to form.</p> <p>22 THE WITNESS: Well, so what I would say,</p> <p>23 and I don't recall exactly what was said during</p> <p>24 the deposition from years ago is that we have used</p>	<p style="text-align: right;">Page 100</p> <p>1 care if we're just suturing up an incision or if</p> <p>2 we're putting a transobturator sling in. We watch</p> <p>3 them regardless of what they're doing.</p> <p>4 What I was saying is that there is the</p> <p>5 potential to injure vasculature from a</p> <p>6 transobturator sling that may not be the same</p> <p>7 vasculature that you would injure in a retropubic</p> <p>8 sling.</p> <p>9 There are retropubic sling placements</p> <p>10 that can injure vasculature that you would not</p> <p>11 injure on a transobturator sling. So we watch</p> <p>12 both of them very carefully.</p> <p>13 BY MS. GAYLE:</p> <p>14 Q. Thank you for that clarification, Doctor.</p> <p>15 You don't -- at this point, Doctor, do</p> <p>16 you use a lot of transvaginal mesh or have you gotten</p> <p>17 away from that?</p> <p>18 MR. WALKER: Object to form.</p> <p>19 THE WITNESS: Well, I wouldn't say I have</p> <p>20 gotten away from it. If I still had Prolift on</p> <p>21 the shelves, I would be using them.</p> <p>22 There have been numerous patients over</p> <p>23 the course of the last few years that I thought</p> <p>24 were outstanding Prolift candidates and</p>
<p style="text-align: right;">Page 99</p> <p>1 both retropubic and transobturator slings, and</p> <p>2 that the retropubic midurethral slings aren't</p> <p>3 really passing as close to some of the pelvic</p> <p>4 vasculature as the transobturator slings do.</p> <p>5 It doesn't change my opinion that the</p> <p>6 transobturator sling is safe and effective. I</p> <p>7 think that's been demonstrated, but there are</p> <p>8 anatomic landmarks that in the correct hands these</p> <p>9 slings can be placed easily in the hands of a</p> <p>10 pelvic surgeon, but when you're talking about a</p> <p>11 first year resident that is fresh out of medical</p> <p>12 school, that they be a little bit shaky and a</p> <p>13 little bit jumpy in the operating room, you just</p> <p>14 want to keep a little bit of a more close eye on</p> <p>15 them.</p> <p>16 BY MS. GAYLE:</p> <p>17 Q. So you would be a little bit observing</p> <p>18 that particular student in your hypothetical a little</p> <p>19 bit more closely if they were implanting a TVT-O versus</p> <p>20 a retropubic, fair?</p> <p>21 MR. WALKER: Object to form.</p> <p>22 THE WITNESS: No, no. I watch -- any</p> <p>23 time I put a knife in the hand of an intern I</p> <p>24 watch them like a hawk, and it doesn't -- I don't</p>	<p style="text-align: right;">Page 101</p> <p>1 unfortunately I did not have Prolift to use in</p> <p>2 those patients, otherwise I would be still using</p> <p>3 it today.</p> <p>4 MR. WALKER: And just again to clarify,</p> <p>5 the question was -- was that both regard to slings</p> <p>6 and pelvic organ prolapse products?</p> <p>7 MS. GAYLE: Yes.</p> <p>8 THE WITNESS: So in terms of slings, yes,</p> <p>9 I still use slings to this day several times per</p> <p>10 week.</p> <p>11 BY MS. GAYLE:</p> <p>12 Q. Okay. Can you estimate how many times</p> <p>13 per week that you still use slings if you had to guess?</p> <p>14 A. Three to five times weekly.</p> <p>15 Q. Okay. And, Doctor, you just said that</p> <p>16 you really liked the Prolift product, paraphrasing your</p> <p>17 words, but can you tell me what you liked about the</p> <p>18 Prolift product specifically?</p> <p>19 A. Well, the Prolift products offered a way</p> <p>20 to improve clinical outcomes, improve long term success</p> <p>21 rates and decrease recurrence rates, decrease</p> <p>22 symptomatic prolapse without increasing the risk of</p> <p>23 postoperative complications, postoperative side effects</p> <p>24 from vaginal surgeries.</p>

<p style="text-align: right;">Page 102</p> <p>1 We are always looking for a way to</p> <p>2 increase long-term efficacy of any type of repair that</p> <p>3 we do in the female pelvic floor and we want to do that</p> <p>4 in such a way that minimize complications.</p> <p>5 Q. Have you used any other manufacturer's</p> <p>6 kit to treat pelvic organ prolapse?</p> <p>7 A. Like I was saying earlier, during my</p> <p>8 fellowship training we used several different types of</p> <p>9 pelvic organ prolapse kits. I still to this day use</p> <p>10 Gynemesh for sacrocolpopexy procedures pretty much on a</p> <p>11 weekly basis.</p> <p>12 Q. Do you remember whose kit you had used</p> <p>13 previously?</p> <p>14 A. You know --</p> <p>15 Q. Other than Johnson &amp; Johnson?</p> <p>16 A. -- during fellowship we used kits from</p> <p>17 Bard. We used kits from Boston Scientific. We used</p> <p>18 kits from AMS.</p> <p>19 Q. Thank you for that clarification, Doctor.</p> <p>20 When you consented a patient for a mesh</p> <p>21 kit such as the Prolift, did you talk to them about the</p> <p>22 specific manufacturers or compare the kits with them</p> <p>23 when you were consenting them?</p> <p>24 A. Compare which kits?</p>	<p style="text-align: right;">Page 104</p> <p>1 Q. I believe you mentioned earlier that</p> <p>2 corporations really didn't matter whose sling or whose</p> <p>3 polypropylene product it was?</p> <p>4 A. Well, I think that's a very broad</p> <p>5 generalized term that I think we probably need to tease</p> <p>6 out a bit.</p> <p>7 I think that there are design differences</p> <p>8 between several mesh manufacturers which is why later</p> <p>9 in my fellowship and after my fellowship I deviated to</p> <p>10 using one type and that was the Prolift procedure, and</p> <p>11 I made that change based on what I considered to be</p> <p>12 some design issues with the other manufacturers' meshes</p> <p>13 that we did not have with Prolift.</p> <p>14 Q. Okay. Is it fair so say that Prolift was</p> <p>15 your device of choice for the more severe prolapse</p> <p>16 patient like Grade III or IV?</p> <p>17 A. No. We used native tissue repairs for</p> <p>18 Stage II, III and IV. We used sacrocolpopexies for</p> <p>19 pelvic organ prolapse. We used transvaginal mesh kits.</p> <p>20 The decision to move between transvaginal</p> <p>21 mesh abdominally placed sacrocolpopexy mesh and native</p> <p>22 tissue was not based solely on the prolapse of the</p> <p>23 patient, but many times was based on several factors</p> <p>24 such as if the patient had ever had a prolapse repair</p>
<p style="text-align: right;">Page 103</p> <p>1 Q. Any of the products?</p> <p>2 A. You mean did I sit down with a patient</p> <p>3 and compare Johnson &amp; Johnson kits to Bard's kits?</p> <p>4 Q. Yes.</p> <p>5 A. No.</p> <p>6 Q. And just to break that down, you know</p> <p>7 what the consent process is, correct, Doctor, informed</p> <p>8 consent?</p> <p>9 A. I do.</p> <p>10 Q. And so that when you're in the informed</p> <p>11 consent with the patient talking about surgical</p> <p>12 correction using a synthetic mesh product, would you</p> <p>13 have compared one product as opposed to the other</p> <p>14 product with the patient?</p> <p>15 A. Not with every patient.</p> <p>16 Q. And would you have compared specific</p> <p>17 manufacturers of the product with the patient?</p> <p>18 A. Unless there was something specific that</p> <p>19 came up in our discussions of -- and if we did have</p> <p>20 those discussions it would have been with patients that</p> <p>21 were moving more toward a mesh augmented repair, but I</p> <p>22 don't recall having a formal discussion as part of our</p> <p>23 routine informed consent process with patients where we</p> <p>24 discussed the differences between the manufacturers.</p>	<p style="text-align: right;">Page 105</p> <p>1 in the past, what was the age of the patient, what was</p> <p>2 the smoking status of the patient, were they obese,</p> <p>3 were they on chronic steroids, were they</p> <p>4 immunocompromised, what is their activity level going</p> <p>5 to be afterwards.</p> <p>6 There are a number of different factors.</p> <p>7 Each one of the patients that ended up getting a native</p> <p>8 tissue, mesh repair or sacrocolpopexy, there was an</p> <p>9 independent review of that patient's medical history</p> <p>10 and a discussion with that patient going over the</p> <p>11 risks, the benefits, the alternatives and indications</p> <p>12 of all of the available procedures, and then letting</p> <p>13 the patient help us decide what was best for them.</p> <p>14 Q. Okay. Doctor, turning to the</p> <p>15 instructions for use which you had mentioned earlier,</p> <p>16 would you agree that the instructions for use are</p> <p>17 required by law to be in as part of -- accompany the</p> <p>18 medical devices that you opinioned on today?</p> <p>19 MR. WALKER: Objection to form.</p> <p>20 THE WITNESS: Sorry. Say that one more</p> <p>21 time.</p> <p>22 BY MS. GAYLE:</p> <p>23 Q. So I will break it down, Doctor. Would</p> <p>24 you agree that the instructions for use are required by</p>

<p style="text-align: right;">Page 106</p> <p>1 law to be in -- were required to law to be in the</p> <p>2 Prolift kit products?</p> <p>3 MR. WALKER: Object to form.</p> <p>4 THE WITNESS: I don't know. Are you</p> <p>5 talking about a state law, a federal law?</p> <p>6 BY MS. GAYLE:</p> <p>7 Q. A federal law, Doctor.</p> <p>8 A. I don't know what the federal law is.</p> <p>9 Q. FDA federal law.</p> <p>10 A. I don't know what the FDA law is and what</p> <p>11 has to be in packaging.</p> <p>12 Q. Okay. And that would apply to all the</p> <p>13 products that you've opined on today, you wouldn't know</p> <p>14 what law would relate to what has to be in the</p> <p>15 packaging, correct?</p> <p>16 A. No, I'm not a legal expert.</p> <p>17 Q. Okay. And, Doctor, do you know if the</p> <p>18 instructions for use for the Prolift talk about use for</p> <p>19 that product in any particular grade of prolapse?</p> <p>20 A. I don't know if it specified that it had</p> <p>21 to be used in a certain grade of prolapse.</p> <p>22 Q. Doctor, you guys use different phrases in</p> <p>23 your profession. Do you know what a revision surgery</p> <p>24 is, Doctor?</p>	<p style="text-align: right;">Page 108</p> <p>1 Q. Okay. Thank you, Doctor.</p> <p>2 A. I can't tell you how many of them were</p> <p>3 mesh and I can't tell you how many of them were</p> <p>4 specific products. Sometimes I don't even know what</p> <p>5 the product is.</p> <p>6 We see a little piece of mesh or we see a</p> <p>7 suture poking through or something. We go back to make</p> <p>8 a revision and sometimes the operative notes that we</p> <p>9 review from the prior procedure don't always tell us</p> <p>10 who the manufacturer was.</p> <p>11 Q. Thank you. Doctor, do you know what a</p> <p>12 FDA 522 order is?</p> <p>13 A. I'm familiar with the FDA 522 process.</p> <p>14 Q. And, Doctor, do you know whether a 522</p> <p>15 order was ever issued on Prolift?</p> <p>16 A. Again, I'm not sure exactly how the 522</p> <p>17 process worked with Prolift. I believe there was, but</p> <p>18 again I'm not sure exactly how that works.</p> <p>19 MS. GAYLE: Go off the record.</p> <p>20 (Off record discussion.)</p> <p>21 BY MS. GAYLE:</p> <p>22 Q. Doctor, again, sorry. Do you know</p> <p>23 whether a 522 order was issued on any of the other</p> <p>24 products that you're opining about today?</p>
<p style="text-align: right;">Page 107</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And just for clarification on the</p> <p>3 record, can you briefly describe what a revision</p> <p>4 surgery in your mind is?</p> <p>5 A. Well, a revision surgery is anything that</p> <p>6 requires that we go back to the operating room and make</p> <p>7 a change. That can be related to over tensioning of a</p> <p>8 device. It can be related to the over tensioning of a</p> <p>9 suture.</p> <p>10 It can be any type of permanent implant,</p> <p>11 whether it is mesh or suture used in a native tissue</p> <p>12 repair that requires that we go back to the operating</p> <p>13 room and make some sort of change, and those revision</p> <p>14 surgeries generally are done if there is a symptom</p> <p>15 related to a surgical procedure, a vaginal surgical</p> <p>16 procedure that is causing some type of symptomatic</p> <p>17 change in the patient that they would like altered.</p> <p>18 Q. Doctor, breaking it down by product, just</p> <p>19 a number, can you tell me approximately how many</p> <p>20 revision surgeries you would have done on the specific</p> <p>21 products that you opined about today?</p> <p>22 A. No, I don't know. I mean I do multiple</p> <p>23 revision surgeries per month. Some of those are mesh</p> <p>24 and some are not.</p>	<p style="text-align: right;">Page 109</p> <p>1 A. I believe they were.</p> <p>2 Q. Can you remember anything specific about</p> <p>3 that process with regard to any particular product?</p> <p>4 A. No. I mean, I'm happy to try to answer</p> <p>5 some questions but I don't remember anything specific.</p> <p>6 I don't know what you're looking for.</p> <p>7 Q. Has anyone ever told you, Doctor, why the</p> <p>8 Prolift was removed from the market?</p> <p>9 MR. WALKER: Object to form.</p> <p>10 THE WITNESS: Why the Prolift was removed</p> <p>11 from the market? I mean I'm sure I've heard from</p> <p>12 several different individuals why Prolift was off</p> <p>13 the market.</p> <p>14 I don't know who would have told me. I</p> <p>15 don't know if it would have been other physicians</p> <p>16 or representatives. I'm not sure.</p> <p>17 BY MS. GAYLE:</p> <p>18 Q. For the record, Doctor, as you sit here</p> <p>19 today, can you briefly explain what your understanding</p> <p>20 is of why the Prolift was removed from the market?</p> <p>21 A. Well, you know, I don't work for Ethicon</p> <p>22 and I don't know what their reasoning was for removing</p> <p>23 the product from the market.</p> <p>24 I know that there were -- I know that</p>

<p style="text-align: right;">Page 110</p> <p>1 there were a lot of FDA warnings that were pretty  2 abhorrent and had a lot of incorrect information that  3 started kind of an anti-mesh frenzy throughout the  4 country, but I don't know. Since I'm not privy to  5 Ethicon's information about why they took it off, I  6 can't tell you exactly why it was removed.  7 Q. Doctor, talking about the FDA warnings  8 and your words that were abhorrent that caused the  9 anti-mesh frenzy, can you explain a little bit more  10 what you're talking about there?  11 A. Sure. I think that they utilized some  12 words and some phrases and didn't actually use good  13 clinical data to drive their statements.  14 Now, they did go back in 2013 and correct  15 some of that, specifically with the sling, the  16 midurethral sling products, they did go back and admit  17 that these were -- these had been shown to be safe and  18 effective in the long-term, and they came to that  19 conclusion only after the FDA went back and did their  20 own systematic review of the medical literature.  21 Prior to their initial statements, we  22 have no indication that they did a systematic review of  23 the medical literature before making their statements.  24 Q. Doctor, just to clarify and clean the</p>	<p style="text-align: right;">Page 112</p> <p>1 A. No, I do not.  2 Q. Is it your usual practice to check the  3 expiration date of a product, synthetic product, before  4 you implant the product in the person?  5 A. Yes, that occurs as part of our timeout  6 in the operating room.  7 Q. To your knowledge, have you ever  8 implanted a product that was past the expiration date,  9 synthetic mesh product?  10 A. Not in the United States.  11 Q. Have you taken that outside the United  12 States?  13 A. I have.  14 Q. In Africa; is that correct?  15 A. Yes.  16 Q. And, for the record, Doctor, can you  17 state what facility you were working at in Africa?  18 A. Ganta, G-a-n-t-a United Methodist  19 Hospital.  20 Q. Doctor, are you aware of whether that  21 facility has burned down also?  22 A. Well, gee. I don't know.  23 Q. I'm just asking if you know.  24 A. Has it?</p>
<p style="text-align: right;">Page 111</p> <p>1 record up. You're using the word "they". Who are you  2 referring to when you say "they"?  3 A. The authors of the FDA reports.  4 Q. FDA personnel?  5 A. Whoever the authors of the report were.  6 Q. Okay. Which report are you speaking of?  7 A. Well, there's several FDA reports. I  8 cited them in my literature. There's a 2011 report and  9 there's a supplement, and then there's a 2013 report.  10 Q. Doctor, after the Prolift was taken off  11 the market, do you recall ever using the Prolift after  12 that time?  13 A. Let's see. I don't know what the dates  14 were. I do -- I can tell you that we got to a point  15 where we were not able to order any more Prolifts in to  16 the hospital and at that time there was an effort on my  17 part to find as many Prolift kits as I possibly could.  18 I think I even asked them to branch out  19 and try to find Prolift kits at other hospitals so that  20 we could continue using those for as long as possible.  21 I think my final Prolift insertion was on a  22 dermatologist from middle Tennessee.  23 Q. Okay. Thank you, Doctor. Do you know  24 what the shelf life of a Prolift kit is?</p>	<p style="text-align: right;">Page 113</p> <p>1 Q. Yes, it has.  2 A. It wouldn't surprise me. When we were  3 there before there were mortar holes and bullet holes  4 in the side of the building large enough to crawl  5 through. So it wouldn't surprise me. They have been  6 in a civil war in Liberia off and on for many years.  7 Q. And, Doctor, how long were you in Africa  8 at that facility?  9 A. We were there for a little more than  10 three weeks.  11 Q. And that was in connection with what time  12 during your --  13 A. Am I being investigated for arson?  14 Q. No, Doctor.  15 A. This is the second --  16 MR. WALKER: I'm struggling with whether  17 or not to object here.  18 BY MS. GAYLE:  19 Q. No, Doctor, I'm just trying to get at  20 when you were in Africa. You have many different  21 places, Doctor, that you were --  22 A. I'm sorry. In two of the places that  23 I've previously worked at you've indicated have burned  24 to the ground after I left.</p>

<p style="text-align: right;">Page 114</p> <p>1 Q. They have, Doctor, so it kind of made it 2 hard to -- 3 A. I'm a little bit. 4 Q. -- to follow where you were at in your 5 resume. 6 A. That was in January of 2009. 7 Q. And which university were you affiliated 8 with? 9 A. I was a fellow at the University of 10 Alabama Birmingham at the time. 11 Q. Thank you, Doctor. 12 MR. WALKER: Which has not burned down to 13 the ground. 14 MS. GAYLE: Which has not burned down to 15 the ground. Thank you, counsel. 16 BY MS. GAYLE: 17 Q. Doctor, do you have a -- I think we 18 talked about earlier when you put your products 19 together you said that they had a lot of general 20 similarities in each of the different reports. 21 A. Yes. 22 Q. And you said earlier also that you used 23 Gynemesh and you still use it today in your 24 laparoscopic sacrocolpopexies, correct?</p>	<p style="text-align: right;">Page 116</p> <p>1 THE WITNESS: Vaginally, correct. Thank 2 you. 3 BY MS. GAYLE: 4 Q. And abdominally, what would you estimate 5 your usage of that has been? 6 A. That's what I was talking about the 200 7 to 500. That is a flat sheet of Gynemesh PS that is 8 trimmed specific to each patient's prolapse. 9 Q. Okay. Thank you, Doctor. What product 10 do you use today for pelvic organ prolapse? 11 A. Well, it depends on the patient. 12 Q. Okay. 13 A. But we do a combination of native tissue 14 repairs, and mesh augmented repairs that we do are all 15 sacrocolpopexies at this point due to our inability to 16 utilize good transvaginal mesh kits. 17 Q. Do you know what the clearance date was 18 for the Gynemesh, flat mesh? 19 A. I'm sorry? 20 Q. The clearance date, the FDA clearance 21 date for the Gynemesh? 22 A. Gynemesh, I believe, was 2002. Somewhere 23 around 2002. 24 Q. Do you know off the top of your head what</p>
<p style="text-align: right;">Page 115</p> <p>1 A. In the robotic sacrocolpopexies, yes. 2 Q. In the robotic. And this Gynemesh is 3 typically a flat piece of mesh that you would trim in 4 the proper shape; is that correct. 5 A. That's correct. 6 Q. Could you estimate how many times you 7 have placed that either robotically, the Gynemesh 8 robotically? 9 A. We probably do three or four per month. 10 So I would estimate that we're doing somewhere between, 11 taking out vacation time, maybe 40 to 50 per year, and 12 started doing those robotically when I came here in 13 2010. So I would say more than 200, less than 500. 14 Q. Thank you, Doctor. And you also as 15 you've indicated earlier that you do the Gynemesh, flat 16 mesh transvaginally as well, correct? 17 A. No. 18 Q. You don't? 19 A. No. 20 Q. Abdominally? 21 A. Correct, and we have utilized -- I have 22 not utilized a flat piece of Gynemesh since I was in 23 fellowship. 24 MR. WALKER: Vaginally?</p>	<p style="text-align: right;">Page 117</p> <p>1 the first launch date for Gynemesh was? 2 A. I'm going to say around the same time. 3 I'm sorry, I don't know the exact date. 4 Q. I'm talking about launch in the United 5 States? 6 A. I would assume around the same time. 7 Q. Doctor, with regard to the IFUs for the 8 products that we talked about, those would be contained 9 as we talked about ad nauseam earlier in your reliance 10 list or within your report, correct? 11 A. They should be in some form or another, 12 yes. 13 Q. Doctor, with regard to the FDA, do you 14 agree with the FDA's viewpoint there's a need for more 15 rigorous study regarding safety and efficacy of mesh 16 kits? 17 MR. WALKER: Objection to form. 18 THE WITNESS: No. No, I think there is 19 always a need for studies that are done in a 20 rigorous fashion to look at long-term efficacy and 21 safety, but do I think that we need studies that 22 are more rigorous than have been in the past? No. 23 I think ongoing studies of adequate rigor 24 are needed in all facets of medicine, not just</p>



<p style="text-align: right;">Page 118</p> <p>1 transvaginal repairs but prolapse repairs in</p> <p>2 general, anti-incontinence repairs in general.</p> <p>3 Robust randomized control trials are a necessary</p> <p>4 part of evidence-based learning.</p> <p>5 BY MS. GAYLE:</p> <p>6 Q. But not specifically any more for and</p> <p>7 with regard to rigorous studies regarding safety and</p> <p>8 efficacy of the mesh kits, correct?</p> <p>9 A. Specifically Prolift?</p> <p>10 Q. Just the mesh kits, mesh exits, synthetic</p> <p>11 mesh kits?</p> <p>12 A. Well, I think if mesh kits are going to</p> <p>13 be marketed then we need studies of that material.</p> <p>14 Either studies that have been previously done on the</p> <p>15 exact mesh material or studies that are looking at a</p> <p>16 specific product that is being rolled out.</p> <p>17 Q. Do you think that there need to be any</p> <p>18 more rigorous studies or studies regarding the safety</p> <p>19 and efficacy for the Prolift kit?</p> <p>20 A. No, I don't think we need any more</p> <p>21 rigorous studies. I think that the randomized</p> <p>22 controlled trials and that the Cochrane reviews looking</p> <p>23 at those randomized controlled trials showed long-term</p> <p>24 efficacy and safety compared to native tissue repairs.</p>	<p style="text-align: right;">Page 120</p> <p>1 Q. 2011 notification?</p> <p>2 A. I can't speak to other physicians and to</p> <p>3 other surgeons. I can tell you that it had no bearing</p> <p>4 on the way that I practiced.</p> <p>5 Q. In fact, you disagreed with that</p> <p>6 July 2011 FDA public health notification?</p> <p>7 A. I disagreed with certain parts of the</p> <p>8 FDA's notification, but not all of it.</p> <p>9 Q. We'll get to that in just a minute,</p> <p>10 Doctor. How do you understand the word rare just so</p> <p>11 that we can sort of go forward on that?</p> <p>12 MR. WALKER: Object to form.</p> <p>13 BY MS. GAYLE:</p> <p>14 Q. How do you understand the word rare when</p> <p>15 it comes to complications?</p> <p>16 A. Well, you know, I think that rare is a</p> <p>17 relative term and everything has their own definitions</p> <p>18 of what they consider rare. So I can't really speak to</p> <p>19 -- since the FDA did not actually utilize a number, I</p> <p>20 can't really speak to what they meant by rare.</p> <p>21 I can, however, speak to what the</p> <p>22 response was to the FDA's safety communication update</p> <p>23 was on what the medical literature actually indicates</p> <p>24 are complications from mesh.</p>
<p style="text-align: right;">Page 119</p> <p>1 Q. Do you know what Ethicon did in response</p> <p>2 to their 522 order on the Gynemesh?</p> <p>3 A. On Gynemesh?</p> <p>4 Q. Gynemesh, the flat mesh.</p> <p>5 A. I'm not sure what you're asking. What</p> <p>6 did they do?</p> <p>7 Q. In response to the 522 order?</p> <p>8 MR. WALKER: Object to form.</p> <p>9 BY MS. GAYLE:</p> <p>10 Q. Did they take any action in response to</p> <p>11 the FDA's 522 order?</p> <p>12 A. You know, I recall something. I'm not</p> <p>13 sure exactly what was done. You know, I think that</p> <p>14 they -- certainly they kept their Gynemesh product, but</p> <p>15 I'm not sure exactly what their response was. I'm not</p> <p>16 sure that I've seen an actual response on it.</p> <p>17 Q. Do you believe it was a reasonable</p> <p>18 decision for a doctor to stop using the Prolift device</p> <p>19 following the July 2011 FDA public health notification?</p> <p>20 MR. WALKER: Object to form.</p> <p>21 THE WITNESS: Do I think it was</p> <p>22 reasonable for a surgeon to stop using Prolift</p> <p>23 after the FDA's --</p> <p>24 BY MS. GAYLE:</p>	<p style="text-align: right;">Page 121</p> <p>1 MS. GAYLE: How long have we been going?</p> <p>2 THE COURT REPORTER: Two hours</p> <p>3 16 minutes.</p> <p>4 THE WITNESS: What I will follow-up with</p> <p>5 that is looking at a response to the FDA's safety</p> <p>6 communication where they indicated that -- where</p> <p>7 the FDA had indicated at least 100,000 prolapse</p> <p>8 repairs were used and about 75,000 of those were</p> <p>9 transvaginal in nature, and the statement</p> <p>10 suggested that 225,000 transvaginal mesh</p> <p>11 procedures were done in a three-year period, and</p> <p>12 in that three-year period there were 1,500</p> <p>13 approximate complications noted from transvaginal</p> <p>14 mesh and that number calculated out as less than</p> <p>15 one percent.</p> <p>16 BY MS. GAYLE:</p> <p>17 Q. And, Doctor, what -- do you have a paper</p> <p>18 there in front of you?</p> <p>19 A. This is one of the response papers</p> <p>20 authored by Miles Murphy and it's a response to the FDA</p> <p>21 safety communication update using the actual numbers,</p> <p>22 which the FDA did not provide.</p> <p>23 Q. Published in what journal, doctor?</p> <p>24 A. This was published in the International</p>



<p style="text-align: right;">Page 122</p> <p>1 Urogynecology Journal.</p> <p>2 Q. And for the record, Doctor, can you just</p> <p>3 state the title of the paper?</p> <p>4 A. Time to Rethink. An Evidence-based</p> <p>5 Response from Pelvic Surgeons to the FDA Safety</p> <p>6 Communication Update on Serious Complications</p> <p>7 Associated with Transvaginal Placement of Surgical Mesh</p> <p>8 for Pelvic Organ Prolapse.</p> <p>9 It's authored by Miles Murphy and</p> <p>10 co-authored by Holzberg, Kohli, Goldman and Lucente.</p> <p>11 Q. Doctor, if the Prolift were available</p> <p>12 today, would you believe that it would be within the</p> <p>13 standard of care to continue to implant the Prolift?</p> <p>14 A. Absolutely.</p> <p>15 Q. And even if it weren't available and you</p> <p>16 found some on the shelf that had not expired, would you</p> <p>17 still believe that it were the standard of care to</p> <p>18 implant the Prolift?</p> <p>19 A. Yes. If there was one on the shelf now</p> <p>20 we wouldn't be able to utilize it now because of it</p> <p>21 being out of date.</p> <p>22 Q. Well, let's just assume that it would be</p> <p>23 in date.</p> <p>24 A. So if you're giving a hypothetical --</p>	<p style="text-align: right;">Page 124</p> <p>1 THE WITNESS: Now, that we're back on the</p> <p>2 record before we get started again I do want to --</p> <p>3 I want to clear two things up that I think were</p> <p>4 some exaggerated claims previously.</p> <p>5 The hospital in West Memphis Arkansas,</p> <p>6 Crittenton, did not burn to the ground. They had</p> <p>7 a fire that broke out in the intensive care unit</p> <p>8 where they had to evacuate 14 patients.</p> <p>9 The hospital who was already seeking</p> <p>10 donations to stay afloat before the fire closed</p> <p>11 their doors a month later. So the hospital didn't</p> <p>12 actually burn down.</p> <p>13 I did text the medical director of Ganta</p> <p>14 United Methodist in Liberia and that hospital also</p> <p>15 did not burn down. There was a fire that they</p> <p>16 believe started from a generator in one of the</p> <p>17 doctor's residence buildings that burned a</p> <p>18 resident's house, a resident building down, but</p> <p>19 did not burn the hospital down.</p> <p>20 BY MS. GAYLE:</p> <p>21 Q. Thank you for that, Doctor, and I wasn't</p> <p>22 inferring that you had started the fire or that you</p> <p>23 were under investigation for arson.</p> <p>24 A. I'm putting it on the record.</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. Hypothetical, Doctor.</p> <p>2 A. -- question, if there were Prolifts still</p> <p>3 available today that were still in date, yes, I think</p> <p>4 that it would still be acceptable to implant a</p> <p>5 transvaginal mesh just like we implant an abdominally</p> <p>6 placed mesh into a patient that has been appropriately</p> <p>7 counseled, that has gone through an informed consent</p> <p>8 process, understands the data and understands the</p> <p>9 long-term efficacy and safety of the products.</p> <p>10 Q. Would that be the same for like the</p> <p>11 Prolift+M product as well, the same answer?</p> <p>12 A. The Prolift+M products, I've used that</p> <p>13 far less than the Prolift product, but we don't have as</p> <p>14 much unfortunately. We don't have as much data on the</p> <p>15 Prolift+M as we do the Prolift.</p> <p>16 What data that we do have showed the</p> <p>17 Prolift+M to be safe and effective, to have similar</p> <p>18 outcomes as the Prolift. So, yes, I think it was also</p> <p>19 a safe and effective means of augmenting certain pelvic</p> <p>20 organ prolapse repair procedures.</p> <p>21 MS. GAYLE: Can we go off the record for</p> <p>22 just one moment.</p> <p>23 (Recess taken.)</p> <p>24 MS. GAYLE: All right. Go ahead.</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. My investigator told me that there were</p> <p>2 fires and that they had burned down in both facilities,</p> <p>3 and so just -- and I was just in that context trying to</p> <p>4 place you as you were at UAB, and then you were in</p> <p>5 Africa and I was trying to get to the connection to the</p> <p>6 two of those.</p> <p>7 MR. WALKER: Let the record reflect the</p> <p>8 doctor's diligence in running facts to the ground.</p> <p>9 BY MS. GAYLE:</p> <p>10 Q. I know. There you are. Again, my</p> <p>11 apologies if you think I was.</p> <p>12 A. No problem.</p> <p>13 Q. Okay. Doctor, so just to kind of wrap up</p> <p>14 a couple of things with regard to your resume. I told</p> <p>15 you that we would get back to that a little bit later.</p> <p>16 So as we discussed, you have a resume at</p> <p>17 Exhibit 8 which is your 2012, your Exhibit 9 resume,</p> <p>18 which was tendered with your reports, as well as your</p> <p>19 exhibit, excuse me, an Exhibit 12 -- Exhibit 8, 9 and</p> <p>20 12 and 12-A. Okay.</p> <p>21 On all of these resumes, Doctor, your</p> <p>22 medical license, you have three medical licenses that</p> <p>23 are issued. You have the state of Arkansas, state of</p> <p>24 Alabama and the state of Tennessee, correct?</p>

<p style="text-align: right;">Page 126</p> <p>1 A. Correct.</p> <p>2 Q. Under the state of Arkansas license you</p> <p>3 have the word retired listed.</p> <p>4 A. Correct.</p> <p>5 Q. When contacting the licensing board in</p> <p>6 Arkansas, they stated they didn't have a retired status</p> <p>7 but an inactive status.</p> <p>8 A. Okay.</p> <p>9 Q. Does that word mean the same thing to</p> <p>10 you, inactive versus retired?</p> <p>11 A. As I understand it, you can default on</p> <p>12 your medical -- on your, sorry, on your medical license</p> <p>13 by not sending in payment or you can request that your</p> <p>14 medical license be retired. That was the terminology</p> <p>15 that was used when I spoke to the medical boards at</p> <p>16 both Arkansas and Alabama.</p> <p>17 So when you're in fellowship not really</p> <p>18 knowing where you're going to end up in practice, you</p> <p>19 don't let your medical license lapse. But rather than</p> <p>20 making payments to keep medical licenses active each</p> <p>21 year, we decided to put them into retirement so that</p> <p>22 they could be reactivated without having to go back</p> <p>23 through the process of applying for a medical license</p> <p>24 again.</p>	<p style="text-align: right;">Page 128</p> <p>1 Thank you, Doctor.</p> <p>2 (Off record discussion.)</p> <p>3 BY MS. GAYLE:</p> <p>4 Q. Doctor, you just made a phone call to</p> <p>5 your office; is that correct?</p> <p>6 A. Yes.</p> <p>7 Q. And you were attempting to clarify, it</p> <p>8 looks like a typographical error on your resume. Could</p> <p>9 you please state what you found out?</p> <p>10 A. I have accidentally transposed the numbers</p> <p>11 three or, sorry, the numbers nine and eight. My</p> <p>12 license number is actually 38971.</p> <p>13 Q. Okay, Doctor. And under license number</p> <p>14 38971, that would be your active license for state of</p> <p>15 Tennessee, correct?</p> <p>16 A. That's correct.</p> <p>17 Q. Thank you for that clarification, Doctor.</p> <p>18 (Exhibit 13 - FDA Article entitled Update on</p> <p>19 serious complications associated with</p> <p>20 transvaginal placement of surgical mesh for</p> <p>21 pelvic organ prolapse, FDA safety communication.)</p> <p>22 BY MS. GAYLE:</p> <p>23 Q. Now, turning back to our discussion about</p> <p>24 the FDA, Doctor, I am handing you what has been marked</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. Okay. Thank you, Doctor. And that would</p> <p>2 apply to both Arkansas and Alabama?</p> <p>3 A. That's correct.</p> <p>4 Q. Thank you for that clarification. And</p> <p>5 then with regard to your license at the state of</p> <p>6 Tennessee, you have license number 39871 on your CV, on</p> <p>7 all of your CVs as far back as I can find.</p> <p>8 A. Okay.</p> <p>9 (Exhibit 20 - Medical License.)</p> <p>10 Q. And, Doctor, I pulled from the Tennessee</p> <p>11 Department of Health your license verification and this</p> <p>12 is what's been marked as Exhibit 20.</p> <p>13 A. Okay.</p> <p>14 Q. And, Doctor, that's not your name. It's</p> <p>15 Dr. Sandra Nichole Feeney is found under that license</p> <p>16 number. And we checked and the state of Tennessee does</p> <p>17 not reissue license or recirculate the numbers.</p> <p>18 A. Okay. So that is obviously a typo on my</p> <p>19 part that has been carried forward for several years</p> <p>20 without my knowledge.</p> <p>21 Q. Could you --</p> <p>22 A. I will take that care of that for one</p> <p>23 second if you want to go off the record.</p> <p>24 MS. GAYLE: If we can go off the record.</p>	<p style="text-align: right;">Page 129</p> <p>1 as Exhibit 13 and we spoke briefly about the July 2011</p> <p>2 publication.</p> <p>3 And do you recognize that document,</p> <p>4 Doctor, as the July 13, 2011 FDA public health</p> <p>5 notification?</p> <p>6 A. Yes, I do.</p> <p>7 Q. Doctor, if you would turn to the second</p> <p>8 page of that notification.</p> <p>9 A. Okay.</p> <p>10 Q. I tried to highlight for you on that one</p> <p>11 too also for your convenience. Doctor, do you see the</p> <p>12 paragraph I highlighted starting with the FDA is</p> <p>13 issuing?</p> <p>14 A. Yes.</p> <p>15 Q. "The FDA is issuing this update to inform</p> <p>16 you that serious complications associated with surgical</p> <p>17 mesh for transvaginal repair or POP are not rare."</p> <p>18 A. Yes, I see that.</p> <p>19 Q. Okay. Do you disagree with the FDA in</p> <p>20 that regard?</p> <p>21 A. I guess I would disagree on what their</p> <p>22 definition of what not rare is. I think we covered</p> <p>23 that a little bit before the break today.</p> <p>24 I think that the terms rare and not rare</p>

Page 130	Page 132
<p>1 are very subjective terms, and what we notice is that</p> <p>2 we don't really find a percentage that the FDA gives us</p> <p>3 of complications versus actual implants, and when you</p> <p>4 look at those numbers of actual implants versus the</p> <p>5 reported complications it's less than one percent.</p> <p>6 Now, we don't -- certainly are not here</p> <p>7 trying to propose that every complication is reported.</p> <p>8 We understand that there are complications that don't</p> <p>9 get reported, but I think across the medical</p> <p>10 literature, in randomized controlled trials, in</p> <p>11 Cochrane databases we find very low rates of</p> <p>12 complications that require any type of additional</p> <p>13 surgical treatment.</p> <p>14 Q. Doctor, after you -- after the issuance</p> <p>15 of this July 13, 2011 FDA notice, did you consult your</p> <p>16 patients about this notice?</p> <p>17 A. We talked about FDA notices, yes, we did.</p> <p>18 Q. What did you tell them about this notice?</p> <p>19 A. Well, we told them that the notice was</p> <p>20 there. I think we discussed some of the terminology in</p> <p>21 the notice and we also discussed that the products for</p> <p>22 pelvic organ prolapse and stress urinary incontinence</p> <p>23 while not actually noted in the FDA's reports had been</p> <p>24 studied in numerous trials and shown to be safe and</p>	<p>1 would be great, which ones you're referring to.</p> <p>2 A. Sure. That's my TVT report.</p> <p>3 Q. The name and date.</p> <p>4 A. Sure. First would be Maher, M-a-h-e-r</p> <p>5 from 2013 as well a 2016 Cochrane review by the same</p> <p>6 author. We also have a 2016 systematic review by Megan</p> <p>7 Schimpf spelled S-c-h-i-m-p-f.</p> <p>8 We have randomized control trials from</p> <p>9 Altman, and I'll have to go back, and I believe that</p> <p>10 was 2011. We have a Withagn, W-i-t-h-a-g-n. That</p> <p>11 trial I would have to go back and look for. I believe</p> <p>12 it was also 2011. Yes, 2011.</p> <p>13 We also have a reference in my report, a</p> <p>14 2012 randomized control trial from Halaska. We have a</p> <p>15 2014 multi-center randomized control trial from da</p> <p>16 Silveira, and all of these are -- we also have</p> <p>17 long-term randomized control trial data from 2016 from</p> <p>18 Dr. Heinonen's group.</p> <p>19 We have a 2011 study from Miller. We</p> <p>20 have studies from Cosson, from Bhatia. We have -- I've</p> <p>21 included some of the studies referenced by plaintiffs'</p> <p>22 expert witness and including Benbouzid's study, Kozal's</p> <p>23 study.</p> <p>24 Q. Would you spell that, Doctor.</p>
Page 131	Page 133
<p>1 effective, and that we would not expect the patients to</p> <p>2 have serious complications if we were doing our jobs</p> <p>3 correctly and if the patients were doing their jobs</p> <p>4 correctly.</p> <p>5 Q. Did you discuss the fact that they had</p> <p>6 said that they were not rare and qualify it with --</p> <p>7 A. Well, I don't recall specific</p> <p>8 conversations where we attempted to define what is rare</p> <p>9 and not rare.</p> <p>10 Q. And I'm just speaking generally, Doctor.</p> <p>11 A. Yes, I mean we may have discussed that at</p> <p>12 some point. Again, I don't recall a specific instance</p> <p>13 where we tried to place a number on rare or not rare.</p> <p>14 We do in our counseling sessions or we</p> <p>15 did in our counseling sessions with individuals that</p> <p>16 were undergoing transvaginal mesh procedures for</p> <p>17 prolapse, talk about several of the risks and the</p> <p>18 percentages that had been listed in our most trusted</p> <p>19 studies.</p> <p>20 Q. Can you list any of those most trusted</p> <p>21 studies off the top of your head?</p> <p>22 A. I'm happy to go through several of them</p> <p>23 with you.</p> <p>24 Q. Just the names, Doctor, and the authors</p>	<p>1 A. Benbouzid is B-e-n-b-o-u-z-i-d. Kozal is</p> <p>2 K-o-z-a-l. I believe those were both referenced by</p> <p>3 plaintiffs' expert witness in some of their reports.</p> <p>4 Q. Do you remember which expert doctor?</p> <p>5 A. I do not. I do not. I just had it under</p> <p>6 the heading of going back and addressing some of the</p> <p>7 expert witnesses statements and their -- we also have a</p> <p>8 Meyer, M-e-y-e-r study that we've addressed. That's</p> <p>9 different from the Maher study.</p> <p>10 And then we have a large list that I</p> <p>11 won't bore you with but it's on pages 34 and 35 of my</p> <p>12 Prolift general statement that lists 15 or 20 different</p> <p>13 studies looking at the generalizable known risks of all</p> <p>14 pelvic organ prolapse surgeries, mesh or otherwise.</p> <p>15 Q. And, Doctor, just to clarify. You said</p> <p>16 on your generalized statement. You mean your report,</p> <p>17 pages 34 and 35?</p> <p>18 A. Of the Prolift general report.</p> <p>19 Q. That would be Exhibit 4, correct, Doctor?</p> <p>20 A. That's correct.</p> <p>21 Q. Thank you, Doctor. So, Doctor, do you</p> <p>22 agree or disagree that there is no evidence that</p> <p>23 transvaginal mesh repair provides any added benefit</p> <p>24 compared to a traditional surgery without mesh?</p>

<p style="text-align: right;">Page 134</p> <p>1 A. I disagree with that statement. We have  2 randomized controlled trials and Cochrane databases  3 that refute that, specifically in the anterior  4 compartment where it has been shown numerous times that  5 mesh augmented anterior repairs have a decreased rate  6 of recurrence compared to native tissue repairs.  7 We have the data looking at recurrence  8 rates following apical procedures that showed similar  9 efficacies to abdominal sacrocolpopexy, which is  10 another mesh augmented procedure.  11 We have references comparing mesh  12 augmented sacrocolpopexy procedures to native tissue  13 repairs that show increased durability and decreased  14 failure rates.  15 Q. Thank you, Doctor. Turning back to our  16 Exhibit Number 13, again on the third page the third  17 bullet point down, Doctor, do you see where it says  18 "there is no evidence that transvaginal repair to  19 support the top of the vagina (apical repair) or the  20 back wall of the vagina (posterior repair) with mesh  21 provides any added benefit compared to traditional  22 surgery without mesh"?  23 A. Yes. So I agree with part of that  24 statement, that we don't have evidence -- well, I won't</p>	<p style="text-align: right;">Page 136</p> <p>1 find --  2 MS. GAYLE: Go off the record.  3 (Off record discussion.)  4 THE WITNESS: Actually I'm not going to  5 speak on the apical because I don't have in my --  6 in my most trusted data, which is the randomized  7 controlled trials here and the Cochrane reviews, I  8 don't have specific bullet points regarding  9 apical.  10 I have them regarding anterior and  11 posterior which I've addressed no benefit to mesh  12 in the posterior compartment, but absolutely no  13 benefit to the mesh augmentation in the anterior  14 compartment.  15 BY MS. GAYLE:  16 Q. Thank you, Doctor. With regard to the  17 first bullet point, do you see that, Doctor?  18 A. Yes.  19 Q. Starting with mesh used in transvaginal  20 POP repair. Do you agree with or disagree with that  21 statement?  22 A. I disagree with that statement.  23 Q. Can you briefly state why you disagree  24 with that?</p>
<p style="text-align: right;">Page 135</p> <p>1 say we don't have evidence.  2 I would say the preponderance of the  3 evidence shows that there is no benefit to placing mesh  4 in the posterior compartment compared to a native  5 tissue repair.  6 What that has not been stratified in to  7 is do we know that that is the data on people who have  8 already had a native tissue repair, had a failure of  9 that repair and ended up going back to the operating  10 room.  11 Again, we have some data that I'm happy  12 to share with you looking at apical support utilizing  13 mesh. It's not necessarily a transvaginal mesh because  14 we don't tend to place mesh at the apex and we tend to  15 place mesh in the anterior/posterior compartments while  16 the abdominal sacrocolpopexies, many people will  17 actually attach the mesh directly to the apex, and  18 that's not something that I have done in patients that  19 are getting transvaginal mesh.  20 Q. Thank you, Doctor. I'm just speaking as  21 regarding this particular bullet point, and you said  22 again you agree in part and you would disagree in part,  23 correct?  24 A. Well, again, give me one second to</p>	<p style="text-align: right;">Page 137</p> <p>1 A. Sure. This says that mesh used in  2 transvaginal prolapse repair introduces risk not  3 present in traditional non-mesh surgery for pelvic  4 organ prolapse, and what I would do is point you to the  5 2013 release from the FDA, almost a response to their  6 own review, and I'll pull that up for you here.  7 Let me go from memory so we don't have to  8 waste time. In a 2013 FDA release they came back and  9 stated that -- they're specifically talking about the  10 mesh used in midurethral slings at this point -- that  11 the known complications of vaginal scarring,  12 dyspareunia, pain, bleeding, that all of the previously  13 known and associated complications that they had quoted  14 to be related to transvaginal mesh were also known  15 complications of native tissue repairs with the sole  16 exception of mesh exposure.  17 That's from -- that's straight from the  18 FDA. I agree with that statement with the exception of  19 the exposure.  20 Now, while you cannot have a mesh  21 exposure without the implantation of mesh, you can have  22 an exposure of implantable material used in native  23 tissue repairs, and I have personally removed implanted  24 permanent material used in native tissue repairs from</p>



<p style="text-align: right;">Page 138</p> <p>1 the bladder, from the urethra, from the vagina, from 2 the rectum, both erosions and exposures. 3 Q. In your clinic, in your practice, in your 4 years being a doctor? 5 A. That's correct, and we have addressed the 6 same complications that the FDA changed course in 2013. 7 This is straight from their report with the exception 8 of mesh erosion the above complications, pain, mesh 9 erosion through the vagina also called exposure, 10 extrusion or protrusion, infection, urinary problems, 11 recurrent incontinence, pain during intercourse or 12 dyspareunia, bleeding, organ perforation, neuromuscular 13 problems, vaginal scarring, can occur following a 14 non-mesh surgical procedure. 15 That is -- what I'm saying is that each 16 one of these problems with the exception of a mesh 17 exposure, we have dealt with in native tissue repairs. 18 In that same vein, however, I have dealt 19 with exposures of implantable materials used in native 20 tissue repairs frequently, removed them from the 21 vagina, from the bladder, from the rectum. 22 So I don't agree with the 2011 FDA 23 statement that says that mesh introduces risk not 24 present in non-mesh surgeries.</p>	<p style="text-align: right;">Page 140</p> <p>1 BY MS. GAYLE: 2 Q. So would you disagree with -- I'm sorry, 3 Doctor. So would you degree with this paragraph where 4 they're talking about mesh contraction is a previously 5 unidentified risk of transvaginal POP repair with mesh 6 that has been reported in the published scientific 7 literature under the adverse event reports to the FDA 8 since the October 20th, 2008 FDA update public health 9 notification? 10 A. You know, I don't think mesh contraction 11 was a previously unidentified risk. Mesh has been 12 around literally for decades and was FDA cleared to be 13 used in the human body back in the 1960s, and surgeons 14 have been aware of different types of complications 15 with any implantable material since that time. 16 So, no, I don't agree that it was a 17 previously unidentified risk. I think that mesh 18 contraction has been known about for some time. I 19 think that clinically relevant mesh contraction is not 20 really something that exists. 21 I think that you do have some contraction 22 of the mesh. I think that that is a normal part of the 23 healing process that occurs in the immediate 24 postoperative period, but we have had several studies</p>
<p style="text-align: right;">Page 139</p> <p>1 Q. Doctor, when you say that you've dealt 2 with these implanted materials when you were doing the 3 native tissue repairs, what kind of implanted materials 4 are you referring to? 5 A. Permanent sutures. 6 Q. Again, I'm sorry? 7 A. Permanent sutures. 8 Q. Any specific type of sutures? 9 A. We have also had complications from 10 cadaver grafts, fascia lata type graphs we've had to 11 address, so both synthetic and biologic issues. 12 Q. Thank you, Doctor. Switching gears just 13 a little bit, Doctor, at the end of that exhibit on 14 page three, if we can look at Exhibit 13. You'll see a 15 paragraph I highlighted for you talking about mesh 16 contraction. 17 A. Sure. 18 Q. At least would you agree when this was 19 published on July 13th, 2011 that the FDA recognized 20 that mesh contraction existed? 21 MR. WALKER: Objection to form. 22 THE WITNESS: Okay. So I can't speak to 23 what the FDA -- where they got their information 24 regarding mesh contraction.</p>	<p style="text-align: right;">Page 141</p> <p>1 looking at so-called shrinkage of mesh that have shown 2 that that is not really the issue that it has been made 3 out to be. 4 We have studies looking not only at 5 so-called mesh shrinkage with TVT and midurethral 6 slings, but we also have studies that have looked at 7 the potential for mesh contraction in pelvic organ 8 prolapse kits that have not shown any clinically 9 significant shrinkage. 10 They have measured total vaginal length 11 in women undergoing pelvic organ prolapse repairs 12 utilizing mesh kits that showed no difference in 13 preoperative and postoperative total vaginal lengths. 14 If you had a significant clinically 15 relevant shrinkage of the mesh, you would expect that 16 the total vaginal length of these women would change 17 preoperatively and postoperatively. 18 Q. And, Doctor, I'm going to stop you just 19 right there -- 20 A. Sure. 21 Q. -- so I understand your testimony. 22 You've used the phrase significant and clinically 23 relevant. 24 A. Correct.</p>



<p style="text-align: right;">Page 142</p> <p>1 Q. Can you explain to me what you mean by</p> <p>2 that phrase?</p> <p>3 A. Well, I think that we plan as surgeons</p> <p>4 for a certain amount of mesh contraction to occur</p> <p>5 during the healing process, which is why as we teach</p> <p>6 residents and other physicians to do mesh augmented</p> <p>7 procedures, whether they are prolapse or incontinence</p> <p>8 in nature, and while companies such as Johnson &amp;</p> <p>9 Johnson and Ethicon teach physicians about mesh</p> <p>10 products, that the knowledge is given to these surgeons</p> <p>11 that there is a certain amount of mesh contraction that</p> <p>12 must be accounted for at the time of the surgery, which</p> <p>13 is why we find midurethral slings being placed in a</p> <p>14 tension-free fashion and why we find pelvic organ</p> <p>15 prolapse kits using mesh be placed without tension so</p> <p>16 that we can allow for that certain known contraction to</p> <p>17 occur.</p> <p>18 Q. And, Doctor, do you know what that</p> <p>19 certain amount is?</p> <p>20 A. It depends on the product. I have seen</p> <p>21 data from 15 percent to 30 percent with contraction for</p> <p>22 pelvic organ prolapse kits, but again I've not seen any</p> <p>23 valid scientific evidence that shows that a clinically</p> <p>24 relevant shrinkage of material that changes the access,</p>	<p style="text-align: right;">Page 144</p> <p>1 implanting the products --</p> <p>2 A. Correct.</p> <p>3 Q. -- as far as the degree of contracture or</p> <p>4 contraction, shrinkage, that a doctor should expect.</p> <p>5 Have you ever seen any materials from the</p> <p>6 corporation that would include what degree to expect?</p> <p>7 A. I may have seen those at some point. I</p> <p>8 can't quote them for you.</p> <p>9 Q. Doctor, on the next page of Exhibit 13 at</p> <p>10 paragraph number or page four, we've talked about</p> <p>11 abdominally placing mesh.</p> <p>12 A. I'll sorry, which page are we on?</p> <p>13 Q. Page four, Exhibit 13. And I've</p> <p>14 highlighted that paragraph for you towards the bottom</p> <p>15 there, Doctor.</p> <p>16 A. Okay.</p> <p>17 Q. Do you agree or disagree with that</p> <p>18 statement from the FDA?</p> <p>19 A. You know, I think that if you get a</p> <p>20 general gestalt from pelvic surgeons they will tell you</p> <p>21 that there is a lower likelihood of having mesh come</p> <p>22 through the vaginal wall on a sacrocolpopexy,</p> <p>23 specifically because you're not making an incision in</p> <p>24 the vaginal wall at the time of the sacrocolpopexy.</p>
<p style="text-align: right;">Page 143</p> <p>1 changes the caliber or changes the length of the vagina</p> <p>2 in a female exists.</p> <p>3 Q. Okay, Doctor. And when you said that</p> <p>4 Ethicon has trained doctors to where they account for</p> <p>5 the mesh, have they told you any sort of number or any</p> <p>6 sort of degree to where you had to account for that?</p> <p>7 A. Well, Ethicon didn't train me to put mesh</p> <p>8 in, so I don't know what they have told people.</p> <p>9 Q. Well, you said Ethicon trains doctors.</p> <p>10 I'm just trying to get to your testimony.</p> <p>11 A. No, I didn't say Ethicon trained doctors.</p> <p>12 Q. Okay.</p> <p>13 A. Ethicon does not train doctors to do mesh</p> <p>14 procedures. Ethicon gives information about their mesh</p> <p>15 products to physicians.</p> <p>16 It's up to the physician at that point to</p> <p>17 determine. The onus is on the physician at that point</p> <p>18 to determine whether or not they should be doing any</p> <p>19 type of pelvic organ prolapse procedure or any type of</p> <p>20 anti-incontinence procedure. It's not Ethicon's place</p> <p>21 to train a physician to do a procedure.</p> <p>22 Q. We'll get to the training part in just a</p> <p>23 minute, Doctor, but I'm just trying to get to you said</p> <p>24 that the -- they must be accounted for when they're</p>	<p style="text-align: right;">Page 145</p> <p>1 However, the only randomized controlled</p> <p>2 trial I'm aware of looking at abdominal sacrocolpopexy</p> <p>3 versus transvaginal mesh actually showed no difference</p> <p>4 in exposure rates.</p> <p>5 Q. Do you remember what the name of that</p> <p>6 trial was?</p> <p>7 A. Sure, I can find that for you.</p> <p>8 MS. GAYLE: Go off the record.</p> <p>9 (Off record discussion.)</p> <p>10 THE WITNESS: Actually, I think that's</p> <p>11 the same one that we talked about earlier. That</p> <p>12 is the Maher, 2011. Laparoscopic Sacrocolpopexy</p> <p>13 Versus Total Vaginal Mesh for Vaginal Vault</p> <p>14 Prolapse, a Randomized Control Trial.</p> <p>15 BY MR. GAYLE:</p> <p>16 Q. So you would disagree with that</p> <p>17 statement; is that correct, Doctor?</p> <p>18 A. What I'm telling you is that that</p> <p>19 randomized controlled trial, which is the not what the</p> <p>20 FDA used to make their statement, the randomized</p> <p>21 control trial, the authors "failed to find a</p> <p>22 statistically significant difference in the rate of</p> <p>23 mesh erosion. They also failed to show a difference in</p> <p>24 quality of life measures."</p>

<p style="text-align: right;">Page 146</p> <p>1 Q. And what year was that?</p> <p>2 A. That's 2011.</p> <p>3 Q. Okay. Thank you, Doctor.</p> <p>4 A. I don't know what month it was available,</p> <p>5 but my assumption would be it would have been available</p> <p>6 at the time the FDA was releasing their updates.</p> <p>7 (Exhibit 14 - Article entitled Safety of Vaginal</p> <p>8 Mesh Surgery Versus Laparoscopic Mesh Sacropexy</p> <p>9 for Cystocele Repair: Results of the Prosthetic</p> <p>10 Pelvic Floor Repair Randomized Controlled Trial.)</p> <p>11 BY MS. GAYLE:</p> <p>12 Q. Thank you. Doctor, I'm going to hand you</p> <p>13 what's been marked as Exhibit Number 14. Doctor, for</p> <p>14 the record, can you read the title of this paper?</p> <p>15 A. Safety of Vaginal Mesh Surgery Versus</p> <p>16 Laparoscopic Mesh Sacropexy for cystocele repair:</p> <p>17 Results of the Prosthetic Pelvic Floor Repair</p> <p>18 Randomized Controlled Trial.</p> <p>19 Q. And, Doctor, if we can look at the</p> <p>20 authors for a moment. Do you know any of these authors</p> <p>21 personally, and I'll give you a moment to look over</p> <p>22 that list?</p> <p>23 A. No, I don't know them personally.</p> <p>24 Q. Do you know or do you recognize any of</p>	<p style="text-align: right;">Page 148</p> <p>1 article you'd like to ask?</p> <p>2 Q. Certainly, Doctor. My question relates</p> <p>3 to their findings that the rate of complications is</p> <p>4 lower after the laparoscopic mesh sacrocolpopexy than</p> <p>5 TVM, and you can look down at the first page at the</p> <p>6 results and the limitations.</p> <p>7 And of course it goes on to say that the</p> <p>8 rate of complications of Grade III or higher were</p> <p>9 nonetheless significantly lower after LS.</p> <p>10 A. Okay.</p> <p>11 Q. It seems from your testimony, and correct</p> <p>12 me if I'm wrong, that you disagree that those rates</p> <p>13 would be lower based on, for instance, the papers that</p> <p>14 you've previously cited?</p> <p>15 A. No, I think you're misquoting what I</p> <p>16 said. I said that among most pelvic surgeons it's</p> <p>17 understood that there could be a increased risk of a</p> <p>18 mesh exposure in a transvaginal case versus abdominal</p> <p>19 sacrocolpopexy.</p> <p>20 We have data that says both, okay? We</p> <p>21 also have different surgeons in different locations,</p> <p>22 some that are skilled in transvaginal mesh, some that</p> <p>23 are very skilled in laparoscopic assisted</p> <p>24 sacrocolpopexy.</p>
<p style="text-align: right;">Page 147</p> <p>1 their names?</p> <p>2 A. I recognize a few of the names, but it's</p> <p>3 not -- it's not anyone that I've had discussions with</p> <p>4 or know on a personal level.</p> <p>5 Q. Okay. Thank you, Doctor. And, Doctor, I</p> <p>6 could not find this article anywhere in your report or</p> <p>7 your reliance materials.</p> <p>8 Have you seen this article before? It is</p> <p>9 a newer article.</p> <p>10 A. Yes, I don't know if I've seen it or not.</p> <p>11 It's a 2018 article.</p> <p>12 Q. All right. You can flip that over if you</p> <p>13 haven't seen it.</p> <p>14 A. Well, again I'll lay it to the side. I'm</p> <p>15 not sure if I've seen it or not. I review a lot of</p> <p>16 articles.</p> <p>17 Q. Okay. This is in the European</p> <p>18 Association of Urology.</p> <p>19 A. Uh-huh.</p> <p>20 Q. Do you read that journal, Doctor?</p> <p>21 A. I have read some articles from that</p> <p>22 journal. I don't have a subscription to that journal</p> <p>23 or have that journal sent to my office.</p> <p>24 Is there a specific question from this</p>	<p style="text-align: right;">Page 149</p> <p>1 It would not surprise me to have</p> <p>2 different rates of exposure between facilities, even if</p> <p>3 you're using the same products because of differences</p> <p>4 in surgical skill level, because of differences in the</p> <p>5 numbers of procedures that those individuals do.</p> <p>6 Q. And what is your interpretation of that</p> <p>7 data?</p> <p>8 A. Of which data?</p> <p>9 Q. You said you have different data and</p> <p>10 different skill sets.</p> <p>11 A. Well, the data that I quoted previously</p> <p>12 stated in their randomized control trial they did not</p> <p>13 see a significant difference.</p> <p>14 Q. Okay. Thank you, Doctor.</p> <p>15 A. Now, one other thing that I think we need</p> <p>16 to point out here. If we're going to compare mesh</p> <p>17 complications or mesh exposures or erosions from mesh</p> <p>18 between transvaginal mesh procedures and abdominal</p> <p>19 sacrocolpopexies or laparoscopic sacrocolpopexies, that</p> <p>20 we should also give some fairness to the discussion of</p> <p>21 other potential complications that occur with both of</p> <p>22 those procedures, and if we're going to state that we</p> <p>23 need to go back to the operating room to perform a</p> <p>24 15-minute procedure where we address a small mesh</p>

<p style="text-align: right;">Page 150</p> <p>1 complication, I would say that anybody would prefer  2 that type of reoperation to a reoperation where we have  3 to go back and open someone's abdomen up again because  4 they have a small bowel obstruction from their  5 abdominal surgery or because they have a large vessel  6 injury around the iliac or because they have some other  7 type of abdominal injury that they're not going to have  8 with a transvaginal mesh procedure.</p> <p>9 So I think if we're talking about  10 post-operative complications we need to be fair in  11 talking about the severity of the complications that  12 can occur after each one of those surgeries.</p> <p>13 Q. And, Doctor, is that your experience or  14 do you have a certain source that you're citing that?</p> <p>15 A. Well, you know, fortunately I have not  16 really had a lot of complications with either of these,  17 but I will tell you that the risks of me injuring  18 someone's aorta on a sacrocolpopexy is a very real  19 possibility. The risk of me damaging someone's aorta  20 on a Prolift is basically zero.</p> <p>21 (Exhibit 15 - Urogynecologic Surgical Mesh:  22 Update on the safety and effectiveness of  23 transvaginal placement for pelvic organ prolapse  24 dated July 2011 from the FDA.)</p>	<p style="text-align: right;">Page 152</p> <p>1 reoperation?</p> <p>2 If you are looking at reoperation rates  3 from recurrent prolapse alone, no. The rate of  4 reoperations for native tissue repairs, for an  5 indication of recurrent prolapse would be higher in the  6 native tissue arm than it would be in the mesh arm.</p> <p>7 The problem with this statement is that  8 they are looking at overall reoperation rates, which  9 not only incur the reoperations for recurrent prolapse  10 but also reoperations for the development of stress  11 incontinence or reoperations to go back in and trim a  12 piece of mesh that became exposed.</p> <p>13 So, yes, the overall reoperation rate in  14 a transvaginal mesh procedure is higher than it would  15 be in a native tissue repair if you're comparing  16 recurrent prolapse, mesh exposures, development of  17 stress urinary incontinence, but again I will go back  18 and state that a reoperation to perform a 15 minute  19 excision of mesh is preferred to a reoperation to  20 address prolapse. So it would not surprise me --</p> <p>21 Q. I'm just -- I'm sorry to interrupt you.  22 I'm just trying to get to --</p> <p>23 A. Well, let me finish my statement.</p> <p>24 Q. -- who think it's preferred?</p>
<p style="text-align: right;">Page 151</p> <p>1 BY MS. GAYLE:</p> <p>2 Q. All right. Thank you, Doctor. You can  3 put that aside.</p> <p>4 Doctor, I'm handing you what has been  5 marked as Exhibit Number 15, and this is the full  6 report of the FDA. It's July 2011 findings. If you  7 would turn to page eight.</p> <p>8 A. Okay.</p> <p>9 Q. And if you'd look at the bullet points.  10 Do you see those, Doctor?</p> <p>11 A. I do.</p> <p>12 Q. The second bullet from the end starting  13 with transvaginal surgery. Do you see that bullet  14 point?</p> <p>15 A. I do.</p> <p>16 Q. If you could read that statement, you may  17 have already discussed this earlier, Doctor. Do you  18 agree or disagree with that statement?</p> <p>19 A. I think that statement needs to be teased  20 apart a bit because that's not a agree or disagree  21 statement.</p> <p>22 Q. Okay.</p> <p>23 A. Are the rates of reoperation from a  24 transvaginal mesh higher than a native tissue</p>	<p style="text-align: right;">Page 153</p> <p>1 A. Let me finish my statement and then you  2 can continue.</p> <p>3 If I have a woman that has a transvaginal  4 mesh procedure that has a small mesh exposure  5 afterwards and I say to her, I didn't get this closed.  6 I got my dissection a little bit wrong. You've got a  7 small little mesh exposure. I apologize profusely.</p> <p>8 Let me take you back to the operating  9 room or let me trim this here in the clinic and let me  10 get this taken care of as opposed to I did a native  11 tissue repair on a diabetic obese patient and she  12 failed.</p> <p>13 Some of these randomized control trials  14 looking at transvaginal mesh, specifically Prolift  15 transvaginal mesh versus native tissue repair showed a  16 less than ten percent recurrence rate in the  17 transvaginal mesh arm, and between 45 and 50 percent  18 recurrence rate in the native tissue repair.</p> <p>19 So I would expect the reoperation rate in  20 a transvaginal rate to be higher because what women is  21 going to say yes, I just went through two months where  22 I wasn't allowed to lift, push or pull anything heavier  23 than five pounds.</p> <p>24 My surgery failed in less than a year and</p>

<p style="text-align: right;">Page 154</p> <p>1 now you want to take me back to the operating room  2 again and do another prolapse repair where you're going  3 to put me on lifting restrictions again two months. I  4 can't lift my grandbaby for another two months. No, I  5 don't want to go back to the operating room and have  6 another three hour prolapse repair where I have to stay  7 in the hospital overnight.</p> <p>8 So, yes, I would expect reoperation rates  9 for small mesh complications to be higher than somebody  10 that says, take me back and let's do it all over again.</p> <p>11 Q. Okay. And, Doctor, for that statement in  12 the sources they list, Caquant, C-a-q-u-a-n-t. I  13 didn't see that in your writings or in your binders or  14 materials, your reliance list or your report.</p> <p>15 Is there any specific reason that you  16 would have excluded an article by that particular  17 author?</p> <p>18 A. I think we must be looking at a different  19 reference list.</p> <p>20 Q. I'm sorry.</p> <p>21 A. I don't see that author.</p> <p>22 Q. Hold on just one second. Sorry, Doctor.  23 I'm just going to strike that question.</p> <p>24 A. Okay.</p>	<p style="text-align: right;">Page 156</p> <p>1 Q. Did you make those orange highlighting  2 marks on your TVT report?</p> <p>3 A. Yes, I did.</p> <p>4 Q. And, Doctor, with regard to the ink  5 handwriting on those reports, is that your handwriting  6 in regard to the things written there in ink on your  7 POP report?</p> <p>8 A. Every word.</p> <p>9 Q. And is that your handwriting with regard  10 to your TVT report?</p> <p>11 A. Every word.</p> <p>12 Q. Okay. So, Doctor, in other words,  13 counsel has not written on or made any markings on  14 those reports for you in advance of the deposition  15 today?</p> <p>16 A. No, they have not.  17 (Exhibit 16 - Cochrane Library Surgery for women  18 with posterior compartment prolapse review.)</p> <p>19 BY MS. GAYLE:</p> <p>20 Q. Thank you, Doctor.  21 I'm handing you what's been marked as  22 Exhibit Number 16. Doctor, if would you turn to page  23 two on that exhibit.</p> <p>24 A. Uh-huh.</p>
<p style="text-align: right;">Page 155</p> <p>1 Q. And, Doctor, you were talking about --  2 earlier you made a remark about the lifting of five  3 pounds. On our break I was able to go through your  4 reports and your markings, which we're going to mark  5 for the record as Exhibit 23 and Exhibit 24.</p> <p>6 MS. GAYLE: The POP report we'll mark as  7 Exhibit 23 that he's marked on and the  8 transvaginal report we'll mark as Exhibit 24 that  9 he's marked on.  10 (Exhibit 23 - POP report with markings.)  11 (Exhibit 24 - Transvaginal report with markings.)</p> <p>12 THE WITNESS: Will you need copies of  13 these?</p> <p>14 MS. GAYLE: Yes, doctor, we will.</p> <p>15 THE WITNESS: We will make copies of  16 those and get them to you.</p> <p>17 BY MS. GAYLE:</p> <p>18 Q. And just to sort of tie up those loose  19 ends, you've got some orange highlighting on your  20 report as well as some ink marks.</p> <p>21 A. Yes.</p> <p>22 Q. Did you make those orange highlighting  23 marks on your POP report?</p> <p>24 A. Yes, I did.</p>	<p style="text-align: right;">Page 157</p> <p>1 Q. I believe, I'm not sure if I highlighted  2 it for you. At the bottom is the page numbers, Doctor.  3 Are you there? It says plain language summary.</p> <p>4 A. Hold on. Yes.</p> <p>5 Q. And if you look down, I'm not sure if I  6 highlighted it, under other comparisons, the last  7 sentence. "The mesh rate in the synthetic group  8 compared with the native tissue group was seven  9 percent." Do you see that?</p> <p>10 A. I do.</p> <p>11 Q. Do you agree with that statement?</p> <p>12 MR. WALKER: Object to form.</p> <p>13 THE WITNESS: Okay. Explain to me. What  14 do you mean do I agree with that statement? Do I  15 agree that in their Cochrane review and comparing  16 their randomized controlled trials that they found  17 a mesh exposure rate of seven percent?</p> <p>18 Yes, I agree that that's what they found  19 in their trial.</p> <p>20 Do I agree that that is a mesh exposure  21 rate that I have experienced with my patients?</p> <p>22 No, I do not.</p> <p>23 BY MS. GAYLE:</p> <p>24 Q. You have, as I understand your testimony,</p>

<p style="text-align: right;">Page 158</p> <p>1 your experiences is that it's lower than seven percent?</p> <p>2 A. My experience is that.</p> <p>3 Q. And as we've talked about today, partly</p> <p>4 some of your opinions today are based on your</p> <p>5 experience as a urogynecologist, correct?</p> <p>6 A. Of course.</p> <p>7 Q. Doctor, if you would take a moment to</p> <p>8 look at the author's conclusions.</p> <p>9 A. Okay.</p> <p>10 Q. And just let me know whether or not you</p> <p>11 agree or disagree with their conclusions, particularly</p> <p>12 the conclusion beginning with the words "evidence does</p> <p>13 not support the utilization of any mesh."</p> <p>14 A. Well, to be more thorough it says</p> <p>15 "evidence does not support the utilization of any mesh</p> <p>16 or graft material at the time of posterior vaginal</p> <p>17 repair", and I think we alluded to that earlier that we</p> <p>18 have randomized controlled trials that do not show a</p> <p>19 difference in mesh augmented and native tissue repairs</p> <p>20 specifically in the posterior compartment. That does</p> <p>21 not hold true to anterior compartment.</p> <p>22 Q. Doctor, if one aim of the POP kit is to</p> <p>23 restore sexual function, would you agree that a POP kit</p> <p>24 should not make it worse?</p>	<p style="text-align: right;">Page 160</p> <p>1 BY MS. GAYLE:</p> <p>2 Q. And, Doctor, I looked through your</p> <p>3 reports, both of them again and your reliance list and</p> <p>4 your supplemental reliance list and I didn't see this</p> <p>5 Cochrane review. I know that you cited the 2016</p> <p>6 Cochrane review.</p> <p>7 Was there any particular reason that you</p> <p>8 didn't cite the 2018 Cochrane review?</p> <p>9 A. This 2018 review?</p> <p>10 Q. Yes.</p> <p>11 A. Well, because the finding of this</p> <p>12 Cochrane review is identical to the finding of the</p> <p>13 other Cochrane review that I listed, that there was no</p> <p>14 difference in mesh augmented or native tissue repair in</p> <p>15 the posterior compartment.</p> <p>16 Q. And that's the sole reason that you</p> <p>17 didn't use the 2018?</p> <p>18 A. It's repetitive if I put that in there.</p> <p>19 Q. And I believe that we've talked about</p> <p>20 some of the repetitive information that you felt that</p> <p>21 you excluded and this would be an example of that</p> <p>22 repetitive information?</p> <p>23 A. Well, so the issue here is that we have a</p> <p>24 Cochrane review that is a culmination of multiple,</p>
<p style="text-align: right;">Page 159</p> <p>1 MR. WALKER: Object to form.</p> <p>2 THE WITNESS: I'm sorry. Say that again.</p> <p>3 BY MS. GAYLE:</p> <p>4 Q. If one aim of the POP kit is to restore</p> <p>5 sexual function in a patient, would you agree that a</p> <p>6 POP kit should not make sexual function worse?</p> <p>7 MR. WALKER: Same objection.</p> <p>8 THE WITNESS: Well, so here that's not</p> <p>9 really a yes or no answer either, so I'll give you</p> <p>10 a quantitative answer.</p> <p>11 Any surgery that is performed inside the</p> <p>12 vagina can lead to dyspareunia. What we have seen</p> <p>13 in multiple randomized control trials and Cochrane</p> <p>14 reviews is an actual increased rate of</p> <p>15 postoperative dyspareunia, painful intercourse in</p> <p>16 patients who were in the native tissue arms of</p> <p>17 studies compared to transvaginal mesh arms of the</p> <p>18 studies.</p> <p>19 We also have an abundance of medical</p> <p>20 literature that's specific to the posterior</p> <p>21 compartments since you offered the Cochrane review</p> <p>22 on posterior surgery, that actually show a</p> <p>23 decrease in dyspareunia following implantation of</p> <p>24 mesh for a indication of rectocele.</p>	<p style="text-align: right;">Page 161</p> <p>1 multiple randomized controlled trials that show that</p> <p>2 there is no benefit of using mesh in the posterior</p> <p>3 compartment.</p> <p>4 What I will also put on the record,</p> <p>5 possibly, you know, against your objection, is that</p> <p>6 many of these studies and Cochrane reviews that we have</p> <p>7 now were not available at the time that surgeons were</p> <p>8 utilizing mesh in the posterior compartment.</p> <p>9 So I don't fault physicians for using</p> <p>10 mesh in a patient who had a prior native repair in the</p> <p>11 posterior compartment that failed, because there were a</p> <p>12 number of studies where people that failed the native</p> <p>13 tissue arm of the study ended up going back to the</p> <p>14 operating room to ultimately have their repair</p> <p>15 finalized using a mesh product.</p> <p>16 Q. Doctor, you're limiting your answer only</p> <p>17 to mesh in the posterior compartment?</p> <p>18 A. I thought that you were speaking</p> <p>19 specifically about mesh in the posterior compartment.</p> <p>20 If you want to talk about mesh in the anterior</p> <p>21 compartment, we can switch gears and talk about that.</p> <p>22 Q. Do you believe that the rate of exposure</p> <p>23 is different in the anterior compartment with the</p> <p>24 native tissue arm?</p>



<p style="text-align: right;">Page 162</p> <p>1 A. I think that the overall exposure rates  2 vary greatly amongst studies and that if one study  3 tells me that they have a two percent mesh erosion rate  4 and another study tells me that they have a 40 percent  5 mesh erosion rate, it doesn't matter to me at that  6 point if it's in the anterior or the posterior  7 compartment.</p> <p>8 What those numbers tell me and what  9 numbers -- we have one randomized controlled trial that  10 actually shows a range of mesh, it's a multi-center  11 randomized controlled trial, that shows a range of mesh  12 exposures from 0 percent to 100 percent. They're  13 utilizing the exact same products.</p> <p>14 Q. Do you remember what the name --  15 A. What that tells me --  16 Q. -- of that study? I'm sorry.  17 A. I can find that for you. What that tells  18 me is that this is an implantation issue, that this is  19 not a design flaw or a problem with the actual mesh.  20 This is a difference in the way that  21 surgeons at one location are implanting mesh,  22 performing their dissections, performing their closures  23 compared to surgeons at another location that may have  24 a mesh complication with every single case they do</p>	<p style="text-align: right;">Page 164</p> <p>1 and training the wrong people, rather that there  2 are surgeons rolling in to various training  3 facilities, whether it be mesh or any other  4 product and doing cases that may not be in their  5 best interest to do.</p> <p>6 I was trained to do bowel resections as  7 part of my fellowship. I can do a bowel resection  8 if I need to.</p> <p>9 I don't do bowel resections here because  10 we have board certified fellowship trained  11 colorectal surgeons that do bowel resections and  12 reanastomosis and complications related to those  13 on a daily basis. So I leave those to the  14 colorectal surgeons to do.</p> <p>15 That is me stepping out of my ego and  16 saying that I don't need to be a cowboy and do a  17 procedure that I may not be well trained to do.  18 So I think that to clarify that statement that it  19 is more of a problem with physicians seeking to be  20 trained, possibly when they don't have the  21 experience or the surgical acumen to perform a  22 procedure, but again that has to fall back to the  23 physician to make their determination of whether  24 or not they should be doing a procedure.</p>
<p style="text-align: right;">Page 163</p> <p>1 because they're not doing the case appropriately.  2 Q. Okay. Do you need to get that?  3 A. I don't that.  4 MS. GAYLE: Go off the record.  5 (Off record discussion.)  6 BY MS. GAYLE:  7 Q. Doctor, in the Vandergriff case in  8 April of 2016 you had testified that "Ethicon and every  9 other company that has been involved in the mesh field  10 has trained way too many physicians that probably  11 should not have been trained."  12 It sounded like earlier you alluded to  13 that fact. Is it still your opinion that only doctors  14 that have done specialized training in urogynecology  15 should be implanting these products?  16 MR. WALKER: Object to form.  17 THE WITNESS: It is my opinion, as I've  18 stated in both of my reports, that the onus falls  19 to the physician to make the determination on  20 whether or not they should be doing a repair.  21 So when I say that mesh corporations have  22 trained too many physicians, it's not necessarily  23 stating that Ethicon or Bard or Boston Scientific  24 or any of these companies are guilty of going out</p>	<p style="text-align: right;">Page 165</p> <p>1 BY MS. GAYLE:  2 Q. Doctor, in your testimony in Vandergriff  3 you described a situation where sometimes doctors would  4 go to these training seminars and, in fact, you had  5 said that you yourself had gone to some and you hadn't  6 even laid your hand on the product, but you would still  7 get a certificate showing that you had actually  8 received training and if you were unethical, which you  9 had said in your testimony that you weren't and you  10 hadn't done this, so I'm not implying that you have,  11 that some doctors would perhaps take that certificate  12 to their hospital and would be able through that means  13 to implant a particular product.  14 A. Yes, that actually occurred in --  15 MR. WALKER: Object to form.  16 THE WITNESS: That actually occurred in  17 one training facility that I went to with one  18 company that I went to, and I never went back to  19 another one of those companies again to implant a  20 product or to one of their seminars and refuse to  21 this day to utilize products from that very  22 corporation, and that was Boston Scientific.  23 BY MS. GAYLE:  24 Q. Okay. I was going to ask you, Doctor,</p>

<p style="text-align: right;">Page 166</p> <p>1 what company that was.</p> <p>2 A. Yes.</p> <p>3 Q. And that has not happened to you?</p> <p>4 A. That has happened that I have seen with</p> <p>5 Johnson &amp; Johnson, Ethicon seminars that I have been to</p> <p>6 in the past. The only place that I ever saw that</p> <p>7 happen was a Boston Scientific lab.</p> <p>8 Q. And certainly, Doctor, again just to</p> <p>9 clarify the record, we're not talking about that you</p> <p>10 have done this, nor am I making that allegation, I'm</p> <p>11 saying that you have witnessed physicians that have</p> <p>12 done this; is that correct?</p> <p>13 A. In the Boston Scientific lab I left with</p> <p>14 a certificate stating that I was -- that I had</p> <p>15 completed training on a product that I did not complete</p> <p>16 training on.</p> <p>17 Q. And, Doctor, you certainly didn't tell</p> <p>18 the hospital that you were equipped to implant that</p> <p>19 product at that point in time since you never laid your</p> <p>20 hands on the product?</p> <p>21 A. No, and I had no intention of ever</p> <p>22 touching that product again.</p> <p>23 Q. Thank you, Doctor. Is it opinion that</p> <p>24 general OB/GYNs should be doing transvaginal mesh kits</p>	<p style="text-align: right;">Page 168</p> <p>1 and board certified. If they have been adequately</p> <p>2 trained.</p> <p>3 We have a -- we have several members here</p> <p>4 at the University of Tennessee that are not board</p> <p>5 certified and are not fellowship trained, and they do</p> <p>6 mesh slings on a regular basis and they do them well,</p> <p>7 and I will take credit for training many of them.</p> <p>8 Q. I was going to ask you, who trained them?</p> <p>9 A. Me.</p> <p>10 Q. And, Doctor, when you trained those</p> <p>11 physicians, did you incorporate, for instance, any</p> <p>12 corporate materials, instructions for use from the</p> <p>13 corporation?</p> <p>14 A. You know, from -- I don't get the best</p> <p>15 follow-up reviews from medical students and I think a</p> <p>16 large portion of that is because I don't turn a medical</p> <p>17 student loose on a patient, and a lot of what I talk</p> <p>18 about in clinic and in the operating room speaks to</p> <p>19 complications that occur with surgeries.</p> <p>20 We discuss warnings. We discuss</p> <p>21 complications. We discuss what happens in the pelvic</p> <p>22 floor when you make incisions in the vagina, when you</p> <p>23 make incisions in the musculature.</p> <p>24 We describe these things ad nauseam</p>
<p style="text-align: right;">Page 167</p> <p>1 for pelvic organ prolapse?</p> <p>2 A. Again, it depends on the OB/GYN. I think</p> <p>3 it depends on their background and their training.</p> <p>4 I think that the majority of prolapse</p> <p>5 procedures and incontinence procedures in today's</p> <p>6 landscape are handled by board certified</p> <p>7 urogynecologists, but I do also feel that there are</p> <p>8 several obstetrician/gynecologists out there that have</p> <p>9 never done a fellowship that are perfectly qualified to</p> <p>10 perform vaginal surgery, to correct prolapse, to</p> <p>11 correct incontinence with and without the use of mesh.</p> <p>12 So I think that's a very broad</p> <p>13 generalizable statement that hopefully I've not made on</p> <p>14 the record in the past. If I have, then I want to</p> <p>15 clarify that I do not think that prolapse and</p> <p>16 incontinence procedures should only be handled by</p> <p>17 urogynecologists.</p> <p>18 I think there are a vast number of</p> <p>19 obstetrician/gynecologists that have the certain</p> <p>20 surgical skill, the education and the training to</p> <p>21 perform these procedures.</p> <p>22 Q. Even if they're not fellowship trained</p> <p>23 and board certified?</p> <p>24 A. Even if they are not fellowship trained</p>	<p style="text-align: right;">Page 169</p> <p>1 throughout the urogynecology rotation, throughout the</p> <p>2 urogynecology conferences, throughout the general</p> <p>3 gynecology conferences, both M &amp; M conferences and</p> <p>4 preoperative conferences as well as Grand Rounds.</p> <p>5 So I hammer into the minds of my student,</p> <p>6 my residents and hopefully one day my fellows that</p> <p>7 these are surgical complications that can occur with</p> <p>8 any type of vaginal procedure.</p> <p>9 So we try as best we had can to make sure</p> <p>10 that every person that leaves the rotation or every</p> <p>11 person that leaves here as a resident or medical</p> <p>12 student leaves with the understanding that it doesn't</p> <p>13 just take a piece of mesh to cause a complication, that</p> <p>14 you can cause the same complication with a suture. You</p> <p>15 can cause the same complication from an overaggressive</p> <p>16 repair of a laceration at the time of the vaginal</p> <p>17 delivery.</p> <p>18 We've been asked to go back and take</p> <p>19 people for reoperations due to overly aggressive</p> <p>20 perineoplasties done at the time of vaginal deliveries</p> <p>21 where there have been laceration. So we try to hammer</p> <p>22 this home that any type of vaginal procedure can lead</p> <p>23 to these complications.</p> <p>24 Q. Doctor, is it your opinion that mesh adds</p>

<p style="text-align: right;">Page 170</p> <p>1 an additional potential problem to surgeries for stress  2 urinary incontinence such as a potential for a foreign  3 body response?  4 MR. WALKER: Object to form.  5 THE WITNESS: No.  6 BY MS. GAYLE:  7 Q. Why not?  8 A. Well, let's compare it to what else we  9 have to treat stress incontinence. If we want to  10 compare it to a Stamey, needle urethropexy or compare  11 it to a Burch or an MMK where we're utilizing permanent  12 sutures, sometimes multifilament permanent sutures that  13 we see, and unfortunately I'll point out that we see in  14 some of the repairs that are done.  15 We have seen extraordinary tissue damage,  16 scarring, the need to take patients back to have  17 permanent sutures removed from their bladder, from  18 their urethra, from their rectums, permanent sutures  19 removed from underneath the vaginal wall and several  20 reconstructive procedures to deal with scar tissue that  21 was leading to dyspareunia so bad that the patients had  22 undergone a divorce, and you go back and you look  23 through their medical record there's no mention of mesh  24 anywhere. This was native tissue repair with permanent</p>	<p style="text-align: right;">Page 172</p> <p>1 We talked about the contraction and the  2 shrinkage earlier today. And, Doctor, do you feel like  3 there's -- mesh adds an additional potential problem to  4 surgeries for stress urinary incontinence such as  5 dyspareunia? I believe you've already discussed that,  6 correct?  7 MR. WALKER: Object to the form.  8 THE WITNESS: No, we have ample evidence  9 that dyspareunia, sexual satisfaction, all improve  10 after the placement of mesh midurethral slings for  11 stress urinary incontinence. That has been shown  12 time and time again in the literature.  13 BY MS. GAYLE:  14 Q. And off top of your head, Doctor, do you  15 know who you're referring to for that?  16 A. Which study we're referring to for that?  17 Q. Yes, Doctor. Thank you.  18 A. I'll give you a list. This is why I have  19 highlights in these. I'm trying to make it easier for  20 me to find one paragraph in a 50 page report, which  21 isn't always easy.  22 The long-term prevalence of dyspareunia  23 in patients receiving midurethral slings for stress  24 urinary incontinence is extraordinary small. In fact,</p>
<p style="text-align: right;">Page 171</p> <p>1 sutures.  2 So, no, I don't agree that these buzz  3 words of chronic inflammatory response, cytotoxicity, I  4 don't think that you can point directly toward a piece  5 of mesh and say this is the implantable material that  6 causes all of this and back it up with actual  7 scientific literature.  8 Q. And, Doctor, and that's the same question  9 I have for you and you mentioned buzz words. So  10 exposure.  11 You don't believe that mesh presents an  12 additional potential problem to surgeries for stress  13 urinary incontinence with regard to exposure?  14 A. So as I stated earlier today with regards  15 to specific mesh exposure, yes. You can't have an  16 exposure of mesh without implanting mesh.  17 With regards to an overall exposure of  18 implanted material, no. We have case upon case upon  19 case of implanted permanent sutures used both in  20 prolapse and incontinence repairs that lead to  21 exposures and erosions and extrusions.  22 Q. Okay. That was going to be my next  23 question, Doctor. I was going to include extrusions in  24 that but you went ahead and did that.</p>	<p style="text-align: right;">Page 173</p> <p>1 multiple studies show improvements in sexual function  2 for sexually active patients treated with mesh  3 midurethral slings for stress urinary incontinence.  4 The authors that I've cited for that  5 statement are Halina Zyczynski in 2012 in a report  6 titled Sexual Activity and Function in Women More than  7 Two Years After Midurethral Sling Placement.  8 Additional citations there were for a  9 report titled Sexual Function Following Retropubic TVT  10 and Transobturator Monarc Sling in Women with Intrinsic  11 Sphincter Deficiency, a Multi-center Perspective Study.  12 That was published in 2012 in the International  13 Urogynecology Journal as well as Mengerink's 2016 study  14 titled The Impact of Midurethral Sling Surgery on  15 Sexual Activity and Function in Women with Stress  16 Urinary Incontinence.  17 Q. Thank you, Doctor. With regard to  18 dyspareunia, you previously testified that there's a  19 number of different reasons why dyspareunia would  20 occur.  21 A. Correct.  22 Q. Improper placement of the mesh, correct?  23 A. Improper placement of mesh or any implant  24 procedure.</p>

Page 174	Page 176
<p>1 Q. That would include whether or not the</p> <p>2 mesh was -- if the dissection plane that the mesh was</p> <p>3 placed in was the wrong dissection plane, correct?</p> <p>4 A. Yes. So let me help you clarify. Do I</p> <p>5 that think the insertion, the proper insertion of a</p> <p>6 mesh midurethral sling causes dyspareunia? No, I</p> <p>7 don't.</p> <p>8 Do I think that the improper insertion of</p> <p>9 a mesh midurethral sling can cause dyspareunia? Yes, I</p> <p>10 think that the improper insertion of a mesh midurethral</p> <p>11 sling can lead to scarring just like the improper</p> <p>12 insertion of a permanent suture for stress urinary</p> <p>13 incontinence can cause vaginal scarring as well as</p> <p>14 dyspareunia.</p> <p>15 So do I think the mesh itself causes the</p> <p>16 dyspareunia? Absolutely not.</p> <p>17 Q. So the improper placement in that</p> <p>18 dissection, is that of a doctor that's a bad doctor?</p> <p>19 MR. WALKER: Object to form.</p> <p>20 THE WITNESS: Well, look, I'm not --</p> <p>21 BY MS. GAYLE:</p> <p>22 Q. Or a poorly trained doctor?</p> <p>23 A. I'm not going to throw him under the bus</p> <p>24 in either of those scenarios, okay? I'm just not going</p>	<p>1 operating room, and the fact that we're having a</p> <p>2 conversation about this I find mind boggling.</p> <p>3 Any surgeon that is willing to take a</p> <p>4 woman to the operating room and put her to sleep</p> <p>5 and cut on her body has an obligation to make sure</p> <p>6 that they are trained to do a procedure before</p> <p>7 they go.</p> <p>8 If you need a valve replacement in your</p> <p>9 heart, please don't come to my office and ask me</p> <p>10 if I'm trained to do that, okay? I'm not. I'm</p> <p>11 not going to make a decision to take somebody to</p> <p>12 the operating room and do something that I'm not</p> <p>13 well trained to do.</p> <p>14 So as I've stated in my reports and here</p> <p>15 today several times, the onus falls to the</p> <p>16 physician to make the determination of whether or</p> <p>17 not they should be doing a procedure.</p> <p>18 BY MS. GAYLE:</p> <p>19 Q. And I appreciate that, Doctor, but again</p> <p>20 do you think that the company has a role in training</p> <p>21 physicians?</p> <p>22 MR. WALKER: Object to form.</p> <p>23 THE WITNESS: I will not say that they</p> <p>24 have a role in training physicians. I do think</p>
Page 175	Page 177
<p>1 to do that. What I will tell you is that I think there</p> <p>2 are different skill sets among physicians and that some</p> <p>3 physicians are better trained than others.</p> <p>4 That being said, I could have a</p> <p>5 complication next week from a midurethral sling that I</p> <p>6 placed and I consider myself to be exceptionally well</p> <p>7 trained. I'm still human. I could make a mistake. I</p> <p>8 could get my dissection plane incorrect. I could get</p> <p>9 my closure incorrect.</p> <p>10 I could have a patient that doesn't</p> <p>11 follow the post-operative restrictions, goes home and</p> <p>12 lifts a 50-pound bale of hay three days after her</p> <p>13 procedure and pops her incision open and exposes her</p> <p>14 mesh. Any of that could happen to me or to a</p> <p>15 non-fellowship trained surgeon.</p> <p>16 Q. Doctor, do you believe that the</p> <p>17 corporations that make these products have any</p> <p>18 responsibility in training physicians?</p> <p>19 MR. WALKER: Object to form.</p> <p>20 THE WITNESS: Well as I said earlier,</p> <p>21 corporations aren't really there to train me how</p> <p>22 to do a procedure.</p> <p>23 It is my responsibility as a surgeon, as</p> <p>24 a pelvic surgeon who is taking women to the</p>	<p>1 that a corporation has a role in educating</p> <p>2 physicians.</p> <p>3 BY MS. GAYLE:</p> <p>4 Q. And how would you expect a company to</p> <p>5 educate physicians?</p> <p>6 A. Well, for instance, Ethicon's Surgeons'</p> <p>7 Resource Monographs. Their availability of training</p> <p>8 opportunities for surgeons to learn. Their</p> <p>9 instructions for use. Their multiple documents that</p> <p>10 they make available for physicians who choose to seek</p> <p>11 out those products, and who choose to do those type of</p> <p>12 procedures. They are there for the taking.</p> <p>13 The problem is that we have several</p> <p>14 physicians and dare I say a generation of physicians</p> <p>15 that don't take the time to seek out data and don't</p> <p>16 take the time to seek out additional training. They</p> <p>17 don't take the time to seek out or to spend the actual</p> <p>18 time learning how to properly do a procedure.</p> <p>19 A physician that wants to learn how to do</p> <p>20 a midurethral sling in my residency program, I don't</p> <p>21 send them to Ethicon and allow Ethicon to teach my</p> <p>22 resident how to do a midurethral sling. I take my</p> <p>23 resident to the operating room and teach them how to do</p> <p>24 a midurethral sling.</p>



<p style="text-align: right;">Page 178</p> <p>1 I don't rely on Ethicon to provide  2 anything to my residents. That resident when they  3 leave this program after four years should be skilled  4 at inserting transobturator slings and retropubic  5 midurethral slings, and I would venture a guess that  6 out of the 16 residents that we have in this program  7 every single one of them will leave this program  8 without seeing an Ethicon representative in this  9 hospital.  10 Q. And, Doctor, would they have seen during  11 the course of your training any of Ethicon's materials  12 like the surgeons' monograph?  13 A. They may have. They may have seen that.  14 They may have seen an IFU.  15 Q. Is that something that you would show  16 them depending on --  17 A. Depending on what the conversation was at  18 that time, yes, but IFUs are readily available in the  19 operating room. It is the role of each physician  20 learner, each resident that walks into the operating  21 room to decide how much they want to learn before they  22 leave that day.  23 If they just want to come in and do  24 enough of the surgery that they can go to their</p>	<p style="text-align: right;">Page 180</p> <p>1 that you talked about, actually from the mesh itself?  2 A. Are you asking about my personal patients  3 or are you asking about patients that are referred to  4 me, because I am a referral center for mesh  5 complications.  6 Q. Break it down both if you wish, Doctor.  7 A. Well, mesh complications that I attribute  8 to the mesh?  9 Q. Yes.  10 A. Zero.  11 Q. Okay. And that would be that are  12 referred or that you have also operated or both?  13 A. Well, so I'm going back again and I'm  14 going to restate what I said from earlier.  15 Do think that a piece of mesh used in  16 prolapse repair or used in an anterior incontinence  17 repair has the ability to cause a complication on its  18 own if it's been placed in an appropriate patient by a  19 skilled physician, in an appropriate manner, in a  20 patient that follows their postoperative restrictions?  21 No, I do not think that there will be any  22 type of mesh complication in a patient like that.  23 Q. And that would go for complications such  24 as degradation?</p>
<p style="text-align: right;">Page 179</p> <p>1 computer and check off their ACGME requirement that  2 they worked on a midurethral sling that day and they  3 have no desire to learn how to do a midurethral sling  4 because when they leave here they're going to do a MFM  5 fellowship. They're going to do amniocentesis every  6 day. That's fine. That's their role.  7 However, if I have a resident that comes  8 in here that is planning on doing a urogynecology  9 fellowship or they're planning on doing pelvic  10 reconstructive procedures when they finish their  11 residency program, you better believe that I expect  12 that resident to do everything that they can do in the  13 operating room, outside the operating room to learn not  14 only about the patient, the implantation of the  15 material, but the complications and the risks that go  16 along with vaginal surgeries. That is what they are  17 here to learn. That's their obligation.  18 Q. Doctor, in your practice, how many  19 clients or patients, excuse me, would you estimate that  20 have had complications from the transvaginal mesh  21 itself?  22 MR. WALKER: Object to form.  23 BY MR. GAYLE:  24 Q. Not a placement issue, none of the issues</p>	<p style="text-align: right;">Page 181</p> <p>1 A. Well, you know, I don't really believe  2 that degradation occurs. We have good scientific data  3 from last year that shows that what has been termed  4 degradation quote unquote in the past is not really  5 degradation of the mesh itself, but more of a cracked  6 layer of the formalin fixation process that occurs  7 after putting the mesh into formalin. It's not an  8 actually degradation of the mesh.  9 We have data that looks at mesh weights  10 pre and post-insertion that shows that their weights  11 are the same. You can't have degradation of a mesh  12 that doesn't lose weight.  13 Q. And, Doctor, that study that you're  14 referring to is Thames, T-h-a-m-e-s; is that correct?  15 A. That's correct.  16 Q. And you have testified earlier this  17 morning that you haven't done any sort of, excuse me,  18 strike that.  19 You haven't published any sort of report  20 on degradation in a peer-reviewed journal, correct?  21 A. I have not.  22 Q. Doctor, does your experience with not  23 having any mesh complication patients or -- strike  24 that.</p>



<p style="text-align: right;">Page 182</p> <p>1 Does your experience as you've just  2 testified with zero complications in your patients  3 attributable to mesh shape some of the opinions that  4 you might have using these products?  5 MR. WALKER: Object to form.  6 THE WITNESS: Well, first of all, I  7 didn't say that I had zero complications. I have  8 an extremely low complication rate.  9 BY MS. GAYLE:  10 Q. Complications attributable to mesh,  11 Doctor.  12 A. So again, if we're teasing this out and  13 saying how many complications do I have in my practice  14 that I would say the mesh caused that problem? None.  15 How many complications have I had in my  16 patients that I could attribute to something that I  17 messed up in the operating room or that the patient  18 messed up by not following restrictions or where a  19 piece of mesh was placed into an inappropriate patient  20 and referred to me for removal or revisions, those  21 patients exist. My complication rate is very low.  22 Q. And I'm just asking with regard to the  23 mesh complications, not a patient factor or improper --  24 A. Well, they are mesh complications still.</p>	<p style="text-align: right;">Page 184</p> <p>1 combination as we've stated several times today of my  2 training, my background, my experiences, and what I  3 have found in the medical literature that bring me back  4 to the same statement every time that these products  5 have been shown and effective for decades.  6 Q. And certainly, Doctor, if you were  7 experiencing lots of or seeing lots of patients where  8 you could say hey, this is evil, in your words, evil  9 mesh could have caused those bucket of patients to have  10 problems, that might change your opinion on the  11 products?  12 MR. WALKER: Object to form.  13 THE WITNESS: No. You know, if I was  14 having a multitude of patients come back into my  15 office with mesh complications, I would start to  16 re-evaluate myself and ask myself whether or not I  17 am skilled enough to be doing these procedures.  18 BY MS. GAYLE:  19 Q. And you wouldn't attribute it at all to  20 anything about the mesh products?  21 A. Based on my education, background,  22 experiences and review of the medical literature, no.  23 Q. Doctor, you talked about the pore size in  24 your report and one of the questions I'd like to ask</p>
<p style="text-align: right;">Page 183</p> <p>1 So I think we need to make sure that we're defining  2 this appropriately.  3 Whether or not I mess something up or  4 another surgeon messes something up or the patient  5 doesn't follow a restriction and they come back in with  6 a complication from their mesh, you can still term that  7 a mesh complication. But do I look at the mesh and say  8 this evil mesh caused this? No, I don't.  9 Q. Okay. Thank you, Doctor, for that  10 clarification. And so you've seen zero where you would  11 say this evil mesh has caused this problem, correct?  12 A. That's correct.  13 MR. WALKER: Object to form.  14 BY MS. GAYLE:  15 Q. Okay. And does that experience help  16 shape your opinions, some of the opinions that you  17 might have using these types of products?  18 MR. WALKER: Object to form.  19 THE WITNESS: I think the products in my  20 hands are perfectly safe.  21 BY MS. GAYLE:  22 Q. So that's a yes, that experience would  23 shape some of your opinions?  24 A. If I -- well, look. You know, it's a</p>	<p style="text-align: right;">Page 185</p> <p>1 you is your knowledge about -- basically about the pore  2 sizes that you talk about, and you've already said that  3 you haven't published anything in a peer-reviewed  4 journal regarding degradation.  5 Have you published anything in a  6 peer-reviewed journal regarding pore size?  7 A. I have not.  8 Q. You testified earlier that sometimes you  9 look at it under a microscope, mesh, and sometimes you  10 have not looked at it under a microscope, correct?  11 A. That's correct.  12 Q. Before you were retained as an expert for  13 Ethicon did you ever talk about pore size to your  14 patients?  15 A. Yes, actually I have. I have told  16 several patients that the type of mesh that we use,  17 this is especially true of patients who come in after  18 they see one of these ridiculous commercials on TV.  19 Patients come in asking about mesh. I  20 have told them that we have ample evidence pointing to  21 the long-term efficacy and safety of macroporous  22 polypropylene mesh and we have talked about the  23 differences between meshes that are macroporous and  24 meshes that are not.</p>

<p style="text-align: right;">Page 186</p> <p>1 Q. And, Doctor, which awful commercials are</p> <p>2 you talking about?</p> <p>3 A. Oh, come on now.</p> <p>4 Q. Now, Doctor I --</p> <p>5 A. I think if you've watched TV anytime in</p> <p>6 the last five years, I bet if I put you under oath you</p> <p>7 wouldn't tell me that you've never seen a commercial</p> <p>8 about mesh complications. So I think we can all stop</p> <p>9 playing games and admit that we know what mesh</p> <p>10 complications are --</p> <p>11 Q. Doctor, I don't have TV. I have Netflix</p> <p>12 actually, so I would ask you --</p> <p>13 A. So you've been watching the Bleeding</p> <p>14 Edge, then.</p> <p>15 Q. Yes. Doctor, so again --</p> <p>16 A. I'm talking about --</p> <p>17 MR. WALKER: Let her ask the question.</p> <p>18 BY MS. GAYLE:</p> <p>19 Q. Again, what type of -- what type of</p> <p>20 commercials, just to clarify the record, Doctor?</p> <p>21 A. So the type of commercials that I am</p> <p>22 talking about are generalized bull, plaintiff attorney</p> <p>23 generated commercials on TV that state if you have had</p> <p>24 one of these mesh products please call the following</p>	<p style="text-align: right;">Page 188</p> <p>1 over the course of the day regarding native tissue</p> <p>2 repairs.</p> <p>3 Again, I didn't see in your report or</p> <p>4 your reliance materials this particular article. Are</p> <p>5 you familiar with this article?</p> <p>6 A. I may have seen it at one point.</p> <p>7 Q. If it was excluded from your report or</p> <p>8 your materials, is there any particular reason that you</p> <p>9 would have excluded it that you can think of?</p> <p>10 A. No, I'll be happy to include it in my</p> <p>11 report. It actually shows here that the pain with mesh</p> <p>12 was 39 percent while the pain with native tissue was 50</p> <p>13 percent. So I wouldn't have a problem including that</p> <p>14 in my report at all.</p> <p>15 Mesh exposure rate was 42 percent in this</p> <p>16 trial and as we've talked about several times there are</p> <p>17 a number of different factors that go into a mesh</p> <p>18 complication.</p> <p>19 One of the things that I'll point out to</p> <p>20 you is that is a this long-term outcome of vaginal mesh</p> <p>21 or native tissue in recurrent prolapse. So this is a</p> <p>22 woman that has already had a recurrence of her</p> <p>23 prolapse.</p> <p>24 That means that she has had a previous</p>
<p style="text-align: right;">Page 187</p> <p>1 number, you may be entitled to compensation.</p> <p>2 Q. Okay. Thank you, Doctor.</p> <p>3 A. Sure.</p> <p>4 Q. Doctor, you do you believe that there is</p> <p>5 a certain pore size that mesh should be to properly</p> <p>6 integrate into tissue?</p> <p>7 A. I think that a macroporous polypropylene</p> <p>8 mesh such that the pore size is above 75 microns has</p> <p>9 been shown safe and effective as an implant in the</p> <p>10 human body since the 1960s.</p> <p>11 MS. GAYLE: Counsel, do you need to take</p> <p>12 a real quick break?</p> <p>13 MR. WALKER: No, just stretching.</p> <p>14 (Exhibit 17 - Document entitled Long-term outcome</p> <p>15 of vaginal mesh or native tissue in recurrent</p> <p>16 prolapse: A randomized controlled trial.)</p> <p>17 BY MS. GAYLE:</p> <p>18 Q. Doctor, I'm going to hand you what's been</p> <p>19 marked as Exhibit 17. And, Doctor, could you read the</p> <p>20 title of that, for the record?</p> <p>21 A. Long-term outcome of vaginal mesh or</p> <p>22 native tissue in recurrent prolapse: a randomized</p> <p>23 controlled trial.</p> <p>24 Q. And, Doctor, we have talked about this</p>	<p style="text-align: right;">Page 189</p> <p>1 repair, which means that she has previous scarring and</p> <p>2 that she is at risk for recurrent prolapse, and the</p> <p>3 people that we find that are at risk for recurrent</p> <p>4 prolapse are obese, smokers, diabetics, the same people</p> <p>5 that have an increased risk of having a complication</p> <p>6 from any implantable material because of their medical</p> <p>7 comorbidities.</p> <p>8 Q. Doctor, on this particular article on</p> <p>9 page 850 or you can look at it as page four under the</p> <p>10 discussion. Oh, I'm sorry, Doctor, this page.</p> <p>11 A. I have 854. I don't have a page four.</p> <p>12 You said 850?</p> <p>13 Q. 850.</p> <p>14 A. Sorry.</p> <p>15 Q. Under discussion.</p> <p>16 A. Yes.</p> <p>17 Q. At the bottom of the second column a</p> <p>18 sentence. Let's see one, two, three, four, five, six</p> <p>19 lines up. It starts with the word one. One should</p> <p>20 consider. Do you see that, Doctor?</p> <p>21 A. Yes.</p> <p>22 Q. That sentence. One should consider,</p> <p>23 however, that total vaginal mesh implants are</p> <p>24 associated with a significantly higher risk of mesh</p>

Page 190	Page 192
<p>1 exposure.</p> <p>2 A. Compared to what?</p> <p>3 Q. That's what they're talking about.</p> <p>4 A. So like you pointed out before you</p> <p>5 started asking questions, I'm not familiar with this</p> <p>6 study. So I'm asking you if you're pointing to this as</p> <p>7 a question, if they are saying that they have a</p> <p>8 significantly higher risk of mesh exposure, I'm asking</p> <p>9 you what are they comparing that to?</p> <p>10 Q. I'm just sort of getting to whether or</p> <p>11 not you have reviewed this or it looks familiar,</p> <p>12 Doctor. You said you would be willing to incorporate</p> <p>13 it into your report, but it's not currently presently,</p> <p>14 right?</p> <p>15 A. Before I would incorporate it into a</p> <p>16 report, I would go back and I would read through this.</p> <p>17 I would find out if it is a viable piece of scientific</p> <p>18 literature.</p> <p>19 If the scientific process was followed</p> <p>20 appropriately and if this was something that we could</p> <p>21 consider to be a viable study and if so, then we could</p> <p>22 happily incorporate these findings into a report,</p> <p>23 because it doesn't change anything.</p> <p>24 You demonstrating one study with a</p>	<p>1 So no author was specifically targeted</p> <p>2 and excluded, and no report was specifically targeted</p> <p>3 or excluded based on the finding of their scientific</p> <p>4 writings.</p> <p>5 Q. Including the authors with adverse</p> <p>6 literature to your opinions?</p> <p>7 A. I have several, several in here that I</p> <p>8 can point to that showed mesh erosion rates in the</p> <p>9 20 percent range.</p> <p>10 Q. And, Doctor, we're going to talk about</p> <p>11 that because you list several opinions where you state</p> <p>12 that plaintiffs' expert or plaintiffs' counsel contend</p> <p>13 one thing or the other.</p> <p>14 A. Sure.</p> <p>15 Q. But you list no citations for that, and</p> <p>16 so I'd like to get to who you're talking about.</p> <p>17 A. Sure, let's go through that.</p> <p>18 Q. We'll get to that in a moment. I also</p> <p>19 noticed that you didn't include any consensus</p> <p>20 statements from the European Urology Association and</p> <p>21 the European Urogynecological Association.</p> <p>22 Was there a particular reason why you</p> <p>23 didn't include those in your reports?</p> <p>24 A. Well, we're not in Europe. You know, I</p>
Page 191	Page 193
<p>1 40 percent mesh erosion rate for every one that you do</p> <p>2 that, I can turn around and show you a similar study</p> <p>3 that has a zero to five percent erosion rate.</p> <p>4 Q. And, Doctor, I noticed in your materials</p> <p>5 and your reliance list, your supplemental reliance list</p> <p>6 and your reports, for instance, that you might have one</p> <p>7 article for a particular author but you maybe didn't</p> <p>8 have additional articles for a particular author.</p> <p>9 Was there any reason that you might have</p> <p>10 excluded some of the author's writings even if it was</p> <p>11 on these subjects?</p> <p>12 A. Well, so I'll take Meyer, for instance.</p> <p>13 I'm sure that Dr. Meyer has written numerous scientific</p> <p>14 articles, and as I pointed out at the beginning of this</p> <p>15 deposition, the articles that I incorporated into this</p> <p>16 I tried to -- whether they were showing low</p> <p>17 complications, high complications, ineffective,</p> <p>18 effective, we try to incorporate randomized controlled</p> <p>19 trials of the highest quality with the longest</p> <p>20 available follow-up.</p> <p>21 We tried to incorporate Cochrane reviews</p> <p>22 that showed a comprehensive picture of mesh procedures</p> <p>23 and non-mesh procedure comparing those in prolapse and</p> <p>24 incontinence patients.</p>	<p>1 think the majority of the scientific bodies that we</p> <p>2 have included in here were ones that I am familiar with</p> <p>3 here in the United States or that have a large presence</p> <p>4 here in the United States.</p> <p>5 International Continence Society,</p> <p>6 International Urogynecologic Association, American</p> <p>7 Urogynecologic Association, AAGL, Society of</p> <p>8 Gynecologic Surgeons, these are all governing bodies</p> <p>9 that have a large presence here in the United States</p> <p>10 that are looked to to provide sound scientific</p> <p>11 reasonable conclusions.</p> <p>12 Q. Doctor, you're a member of AUGS, correct?</p> <p>13 A. I am.</p> <p>14 Q. And, in fact, AUGS, I believe was one of</p> <p>15 the societies that you've been a member of for quite</p> <p>16 some time, correct?</p> <p>17 A. Yes.</p> <p>18 Q. Do you remember when again?</p> <p>19 A. I don't. It's in my CV.</p> <p>20 Q. Okay. Doctor, this is an update dated</p> <p>21 February 13, 2018 on vaginal mesh with prolapse and</p> <p>22 incontinence and they talk about on the second page</p> <p>23 that the Scottish government had released an</p> <p>24 independent review of the safety and efficacy of mesh</p>

<p style="text-align: right;">Page 194</p> <p>1 in their findings, and that the current evidence does  2 not indicate any additional benefit. I did not see  3 that information in there.</p> <p>4 Was there a particular reason that you  5 didn't include that information or is it the same  6 answer as you just gave?</p> <p>7 A. Well, this is a similar statement to what  8 we have from our governing body here in the United  9 States, the FDA. So, you know, I can go back and if  10 you want to give me information, I can turn into this  11 150 page report, but for the sake of trying to keep  12 things concise and for the sake of trying to use the  13 largest governing bodies that people here that would be  14 involved in trials and depositions in the United States  15 would be familiar with, I tried to keep it concise.</p> <p>16 Q. So you have no opinion as you sit here  17 today whether you agree or disagree with those bodies?</p> <p>18 A. I would have to take the Scottish review  19 and sit down and go through that, and I'm happy to do  20 that if you'd like.</p> <p>21 Q. The same thing with the UK review?</p> <p>22 A. Sure.</p> <p>23 Q. Same thing with the Australian review?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 196</p> <p>1 know as SUFU.</p> <p>2 That joint statement said that this  3 procedure, the mesh midurethral sling for stress UI is  4 probably the most important advancement in the  5 treatment of stress urinary incontinence in the last  6 50 years and has the full support of our organizations  7 which are dedicated to improving the lives of women  8 with urinary incontinence, and there was a supporting  9 list of organizations that signed on to that, including  10 AAGL, ACOG, the National Association for Continence,  11 International Urogynecologic Association as well as the  12 Society of Gynecologic Surgeons.</p> <p>13 I also reference in here that the Royal  14 Australian and New Zealand College of Obstetrics and  15 Gynecologists had stated in their 2018 position  16 statement that in the case of stress urinary  17 incontinence and the use of midurethral sling, this  18 surgery has been extensively reviewed with numerous  19 high quality studies. Overall the safety profile has  20 found to be very good with high success rates. In most  21 cases women's quality of life and sexual function  22 improved significantly after this surgical  23 intervention.</p> <p>24 Q. So you did review the Australian</p>
<p style="text-align: right;">Page 195</p> <p>1 Q. Same thing with the New Zealand review?</p> <p>2 A. Correct.</p> <p>3 Q. And you haven't done that, have you,  4 Doctor?</p> <p>5 A. I think I may have alluded to one in my  6 report. I'm not sure. It might have been the New  7 Zealand. I'm not sure. I'd have to go back and look  8 through there. I can do that.</p> <p>9 Q. Yes.</p> <p>10 MS. GAYLE: If you want to go off the  11 record. But Madam Court Reporter, before we do  12 that we are going to mark that as 22 if I didn't  13 already say that. Thank you.</p> <p>14 (Exhibit 22 - AUGS document entitled Update on  15 Vaginal Mesh for Prolapse and Incontinence dated  16 March 2017.)</p> <p>17 BY MS. GAYLE:</p> <p>18 Q. Doctor, did you find that references?</p> <p>19 A. I did, yes. This is on page 36 of my TVT  20 report. This is talking about the FDA's -- this is  21 talking about the FDA's statements as well as the  22 responses from the American Urogynecologic Society and  23 in conjunction with the Society of Urodynamics Female  24 Pelvic Medicine and Urogenital Reconstruction otherwise</p>	<p style="text-align: right;">Page 197</p> <p>1 findings?</p> <p>2 A. I reviewed their position statement from  3 2018.</p> <p>4 Q. Okay. Thank you, Doctor. Doctor, if we  5 can look back to your reports at Exhibit 7 and  6 Exhibit 4 and place them in front of you.</p> <p>7 Exhibit 4 being page 13, and Exhibit 7  8 being page 14, and we kind of talked about this  9 earlier, Doctor, where we had some repetitive language  10 in the report and I think you talked about how some of  11 that might have been cut and pasted or copied over like  12 your qualifications and so forth.</p> <p>13 A. Uh-huh.</p> <p>14 Q. Looking at Section D on that page, the  15 language for both reports seems again to mirror each  16 other except for the words that I've circled for you  17 with regard to pelvic organ prolapse on Exhibit 4 and  18 stress urinary incontinence on Exhibit 7, and the last  19 of then the phrase where it ends with high failure  20 rates, and the last of that sentence on Exhibit 7 and  21 high complication rates patients were experiencing with  22 previously available repairs.</p> <p>23 A. So I see two sentences here that are  24 almost identical.</p>

Page 198	Page 200
<p>1 Q. Okay.</p> <p>2 A. And the reasoning behind that is that</p> <p>3 these are mesh augmented surgical repair procedures,</p> <p>4 and that there is a certain amount of overlap when you</p> <p>5 talk about mesh augmented repairs and those statements</p> <p>6 are based on years of good scientific data that show</p> <p>7 what the procedure's efficacy is, and trying to outline</p> <p>8 for people that may be lay persons what the overall</p> <p>9 goals of correction of prolapse and urinary</p> <p>10 incontinence are, and those are to restore anatomic</p> <p>11 function and anatomic support and to hopefully provide</p> <p>12 good scientific evidence that in order to help restore</p> <p>13 anatomic function that some -- that some patients</p> <p>14 benefit from the use of mesh.</p> <p>15 Q. Thank you for that clarification, Doctor.</p> <p>16 And then on page 14 of Exhibit 4 and page 16 of</p> <p>17 Exhibit 7 you have another paragraph beginning with the</p> <p>18 words polypropylene in Exhibit 4.</p> <p>19 Polypropylene despite assurances from</p> <p>20 plaintiff's counsel has been shown safe and effective</p> <p>21 for decades, and then again if you look at Exhibit 7 it</p> <p>22 says polypropylene with a clause that I've circled for</p> <p>23 you, material make-up of the TVT despite assurances</p> <p>24 from plaintiff's counsel has been shown safe and</p>	<p>1 safety section of Exhibit 7 and I don't think we</p> <p>2 actually have a safety section on Exhibit 4.</p> <p>3 If we do, it may not be labeled exactly</p> <p>4 the same because these two reports were prepared at</p> <p>5 separate times. So I think that I reiterated that just</p> <p>6 as a means of showing the FDA had deemed that product</p> <p>7 safe and effective.</p> <p>8 Q. And, Doctor, what I couldn't figure out</p> <p>9 though is when you copied it from page 16 and</p> <p>10 reiterated it on page 28 on Exhibit 7, the one</p> <p>11 difference you left out is at the end of the second to</p> <p>12 last sentence where on page 16 the clause is but</p> <p>13 surgeries throughout the body, but on page 28 --</p> <p>14 A. I'm sorry. Which page is that on again?</p> <p>15 Q. Page 16, and you'll see the phrase three</p> <p>16 lines from the bottom, but surgeries throughout the</p> <p>17 body.</p> <p>18 A. Okay.</p> <p>19 Q. And then in the next -- in the copy</p> <p>20 material on page 28 --</p> <p>21 A. Yes.</p> <p>22 Q. -- you leave that off.</p> <p>23 A. Right.</p> <p>24 Q. Is there a specific reason for that?</p>
Page 199	Page 201
<p>1 effective for decades.</p> <p>2 That sentence along with much of the rest</p> <p>3 of the paragraph is repetitive in both reports. Is</p> <p>4 this also because that information crosses over?</p> <p>5 A. Yes. They are both the material make-up</p> <p>6 of the TVT and the material make-up of the Prolift are</p> <p>7 polypropylene. So, yes, there's a certain amount of</p> <p>8 overlap as I stated earlier in mesh materials used for</p> <p>9 pelvic organ prolapse and stress incontinence.</p> <p>10 This is a very generalized paragraph that</p> <p>11 is there specifically to point out that these materials</p> <p>12 are polypropylene and that polypropylene had been</p> <p>13 deemed safe and effective by the FDA originally back in</p> <p>14 1969.</p> <p>15 Q. And, Doctor, if you would turn to</p> <p>16 Exhibit 7 on page 28. You have nearly the exact</p> <p>17 language again that we have just read.</p> <p>18 A. Yes. Yes. It's a very long report.</p> <p>19 Q. Is there any reason that you copied that</p> <p>20 paragraph twice?</p> <p>21 A. Yes. It's a very long report, and I feel</p> <p>22 that -- I felt that it was necessary to try to break a</p> <p>23 50 page report down into appropriate sections, and some</p> <p>24 of that information on polypropylene I put into the</p>	<p>1 A. No, nothing nefarious there just -- and I</p> <p>2 think that goes to the point that I made earlier, not</p> <p>3 all of this is an episode where I've copied and pasted</p> <p>4 a paragraph.</p> <p>5 Some of this, as I've stated earlier, is</p> <p>6 me dictating my thoughts into a report. So there may</p> <p>7 be sentences that look very similar in nature that may</p> <p>8 have one or two words that are differing, but I assure</p> <p>9 you there's no nefarious design there in those</p> <p>10 admissions.</p> <p>11 Q. And again if they transfer, the language</p> <p>12 transferred from one report to the other, you would</p> <p>13 simply put that language in your other report, correct?</p> <p>14 A. Depending on what the language was, yes.</p> <p>15 Q. But if the language transferred?</p> <p>16 A. If the language transferred, I would use</p> <p>17 some of the language from one report in to another as</p> <p>18 long as it wasn't anything that was specific to a</p> <p>19 certain product that did not cross over.</p> <p>20 Q. And, Doctor, in both reports you make a</p> <p>21 statement when you're talking about the polypropylene</p> <p>22 in that particular paragraph. You say "despite</p> <p>23 assurances from plaintiff's counsel".</p> <p>24 A. Sure.</p>



<p style="text-align: right;">Page 202</p> <p>1 Q. What assurances are you talking about?</p> <p>2 A. Oh, well, again these TV commercials.</p> <p>3 This is all plaintiff's counsel TV commercials that we</p> <p>4 see that are making references to mesh migration and</p> <p>5 references and innuendos that mesh can crawl around the</p> <p>6 body and wreck havoc, and it's just a generalized term,</p> <p>7 and I think if general -- if plaintiff's counsel and</p> <p>8 plaintiff's expert want to come forward and say that</p> <p>9 they don't believe that, well I'd be happy to hear it.</p> <p>10 Q. And, Doctor, again I'm just trying to get</p> <p>11 to sort of the source of what you're referencing there</p> <p>12 so --</p> <p>13 A. Well, I think my source is a combination</p> <p>14 of seeing commercials on TV. My source is being</p> <p>15 deposed several times in the past by plaintiffs'</p> <p>16 counsel who as you have done today tend to word</p> <p>17 questions in such a way that makes the mesh seem to be</p> <p>18 a dangerous product, when I as a surgeon, researcher,</p> <p>19 and scholar know that that's not the case.</p> <p>20 Q. And, Doctor, I haven't tried to word my</p> <p>21 questions where it makes mesh seems as a dangerous</p> <p>22 product. Again, as I've told you many times my job is</p> <p>23 just to get to the basis of your opinions.</p> <p>24 And in one report you do cite your</p>	<p style="text-align: right;">Page 204</p> <p>1 reports, I think it will be abundantly clear what I'm</p> <p>2 saying here, but I do know some of these people on a</p> <p>3 personal level, and I'm not going to take a colleague</p> <p>4 and throw them under the bus and try to make them look</p> <p>5 foolish which would be played out in courtroom dramas</p> <p>6 over and over and over again.</p> <p>7 What I will say is that in the reports,</p> <p>8 the general reports as well as the case specific</p> <p>9 reports that I have reviewed, that I have seen multiple</p> <p>10 experts make claims, unsubstantiated claims of</p> <p>11 cytotoxicity, chronic inflammation, degradation and</p> <p>12 everything else that I have listed here.</p> <p>13 So while I have not named them, rest</p> <p>14 assured that if I have made a claim that plaintiffs'</p> <p>15 experts have made claims in their statements it has</p> <p>16 been something that I have seen.</p> <p>17 Q. And, Doctor, it's not my job to go</p> <p>18 through those reports and to find the language that</p> <p>19 you're referencing.</p> <p>20 A. And if my counsel --</p> <p>21 MR. WALKER: Let her finish.</p> <p>22 BY MS. GAYLE:</p> <p>23 Q. And so what you're telling me is is that</p> <p>24 your counsel has instructed you not to say what the</p>
<p style="text-align: right;">Page 203</p> <p>1 sources periodically and the other report it's devoid</p> <p>2 of citations and so --</p> <p>3 A. Can you point to the area where I'm</p> <p>4 devoid of citations?</p> <p>5 Q. Particularly in the section on Exhibit 7,</p> <p>6 for instance, when you're talking about plaintiffs'</p> <p>7 counsel and/or plaintiffs' experts.</p> <p>8 So I'm just trying to figure out, for</p> <p>9 instance, page 29, you're talking about mesh</p> <p>10 degradation.</p> <p>11 A. Sure.</p> <p>12 Q. And you say any suggestions by</p> <p>13 plaintiffs' counsel regarding mesh degradation are not</p> <p>14 supported by reasonable medical literature.</p> <p>15 A. Correct.</p> <p>16 Q. Again, I'm trying to figure out which</p> <p>17 plaintiffs' counsel, who you're talking about?</p> <p>18 A. I didn't make any names. I didn't place</p> <p>19 names in here and --</p> <p>20 Q. Can you tell us who you're talking about?</p> <p>21 A. I tell you what we'll do. I have, with</p> <p>22 discussions with counsel, I have made a decision not to</p> <p>23 call out any of the plaintiffs' experts.</p> <p>24 If you go through plaintiffs' experts'</p>	<p style="text-align: right;">Page 205</p> <p>1 basis --</p> <p>2 A. No, you're putting words in my mouth. I</p> <p>3 didn't say that.</p> <p>4 Q. You said under your counsel you have --</p> <p>5 A. I have made the decision after</p> <p>6 discussions with counsel. I have made that decision.</p> <p>7 Q. Now, is this your counsel that's</p> <p>8 representing you on a personal level or your counsel</p> <p>9 representing you in your expert capacity?</p> <p>10 MR. WALKER: Hang on. This is getting</p> <p>11 out of hand. First of all, you're not going to go</p> <p>12 into anything that you and I have discussed.</p> <p>13 Second of all, I think he's being very</p> <p>14 clear he's talking about decisions he's making out</p> <p>15 of professional courtesy to his colleagues and I</p> <p>16 think that's the scope of what is going on.</p> <p>17 THE WITNESS: Correct.</p> <p>18 MS. GAYLE: Well, we can't be here trying</p> <p>19 to discover the basis of his opinion when he's</p> <p>20 going to call out his colleagues and then not cite</p> <p>21 who --</p> <p>22 THE WITNESS: The basis --</p> <p>23 MS. GAYLE: -- and not cite who he is</p> <p>24 referencing. We have the right to figure out what</p>

<p style="text-align: right;">Page 206</p> <p>1 he's referring to in this material.</p> <p>2 MR. WALKER: And that information is</p> <p>3 found in great detail on his reliance list for the</p> <p>4 specific expert reports that he has been sent and</p> <p>5 reviewed are itemized.</p> <p>6 MS. GAYLE: We can't be expected to find</p> <p>7 out what language he is quoting. We don't know</p> <p>8 where this comes from and then he's also saying</p> <p>9 plaintiffs' counsel. Which plaintiffs' counsel?</p> <p>10 THE WITNESS: You've not read plaintiffs'</p> <p>11 experts reports?</p> <p>12 MS. GAYLE: Excuse me.</p> <p>13 MR. WALKER: Hang on.</p> <p>14 MS. GAYLE: Which plaintiffs' counsel?</p> <p>15 We have again, we have to the right to figure out</p> <p>16 what sources and what his basis of his opinions</p> <p>17 are, and so if he claims that plaintiffs' counsel</p> <p>18 has made that we have the right to say that.</p> <p>19 He uses that phrase repetitively</p> <p>20 throughout his report, and so if his response is</p> <p>21 hey, I'm not going to name them, then he can't</p> <p>22 tell me who his sources are and so that we can</p> <p>23 pull up that particular expert's report and then</p> <p>24 look at what he's talking about and trying to</p>	<p style="text-align: right;">Page 208</p> <p>1 A. Sure.</p> <p>2 Q. And you can't tell me who you quoted?</p> <p>3 A. Several of them.</p> <p>4 Q. Which is?</p> <p>5 A. In the reliance list.</p> <p>6 Q. And plaintiffs' counsel, your references</p> <p>7 to those, would you like to list the counsel that you</p> <p>8 attribute to as the source?</p> <p>9 MR. WALKER: Object to form.</p> <p>10 THE WITNESS: As I said earlier, I have</p> <p>11 been deposed several times by plaintiffs' counsel</p> <p>12 plural, that have made claims in their statements</p> <p>13 and in their questioning of mesh products.</p> <p>14 I did not name them. I have not named</p> <p>15 you. I'm not talking about you, but there have</p> <p>16 been instances where I have had discussions with</p> <p>17 plaintiffs' counsel where they have made these</p> <p>18 assurances.</p> <p>19 There have also been instances, since</p> <p>20 we're getting into my discussions with plaintiffs'</p> <p>21 counsels, there have also been instances where we</p> <p>22 have gone off the record and plaintiffs' counsel</p> <p>23 had admitted to me that if their wife needed a</p> <p>24 mesh midurethral sling, they would have no problem</p>
<p style="text-align: right;">Page 207</p> <p>1 rebut?</p> <p>2 THE WITNESS: The sources are in the</p> <p>3 reliance list.</p> <p>4 BY MS. GAYLE:</p> <p>5 Q. So --</p> <p>6 A. Have a perusal through the reliance list,</p> <p>7 review the plaintiffs' experts' reports and you will</p> <p>8 find that information.</p> <p>9 Q. So you can't say which plaintiffs' expert</p> <p>10 talked about mesh degradation?</p> <p>11 A. I already stated several times that</p> <p>12 several of the experts' reports that I read had similar</p> <p>13 information in them, almost as if they had been copied</p> <p>14 and pasted between plaintiffs' experts, similar</p> <p>15 information.</p> <p>16 Q. Doctor, if you're rebutting something</p> <p>17 from one of our experts, if these cases were to go to</p> <p>18 trial, we would need to know whose opinion you're</p> <p>19 specifically rebutting?</p> <p>20 A. And if you want to give me a plaintiffs'</p> <p>21 experts' report during a trial to review, I would be</p> <p>22 happy to rebut their claims?</p> <p>23 Q. We're talking about the ones that you've</p> <p>24 quoted, Doctor.</p>	<p style="text-align: right;">Page 209</p> <p>1 with them having a mesh midurethral sling, that</p> <p>2 they understood mesh that wasn't a problem.</p> <p>3 So if you want to get into conversations</p> <p>4 about what I've spoken with plaintiffs' counsel, I</p> <p>5 will be happy to do that, but I'm not going to</p> <p>6 name people by name.</p> <p>7 BY MS. GAYLE:</p> <p>8 Q. And that is the basis of your opinions</p> <p>9 that you're setting out today?</p> <p>10 MR. WALKER: Objection to form.</p> <p>11 THE WITNESS: Correct. That's -- that is</p> <p>12 a partial basis of my opinions.</p> <p>13 BY MS. GAYLE:</p> <p>14 Q. Thank you, Doctor. If you would turn to</p> <p>15 page 30 on Exhibit 7.</p> <p>16 A. Okay.</p> <p>17 Q. Doctor, the second paragraph again it</p> <p>18 starts with plaintiffs' counsel.</p> <p>19 A. Uh-huh.</p> <p>20 Q. Talking about intraoperative and</p> <p>21 postoperative complications and just again, just to run</p> <p>22 through it in the report just for clarity of the</p> <p>23 record, you're not going to discuss who that was,</p> <p>24 correct?</p>

<p style="text-align: right;">Page 210</p> <p>1 A. I will have further discussions with 2 defendant counsel about that and if they feel that's 3 appropriate then we'll do that, but at this time, and I 4 am not going to name names from the plaintiffs' expert 5 or counsel.</p> <p>6 MS. GAYLE: So pending the outcome of 7 those discussions, counsel, I would reserve my 8 right to depose the doctor again to get to those 9 sources, but you can of course advise me of what 10 your advice is to him about this.</p> <p>11 MR. WALKER: I've already made my 12 position clear. I think you've asked this a 13 number of different times and every single report 14 that he's reviewed is on the reliance list, and --</p> <p>15 THE WITNESS: And every single 16 deposition.</p> <p>17 MR. WALKER: Hang on. And every specific 18 design defect allegation that he is addressing is 19 reflected in the report, and I think it's very 20 clear that almost all of the plaintiffs' experts' 21 reports contain the same basic design defect 22 allegations and that's what he's tackling in the 23 report.</p> <p>24 BY MS. GAYLE:</p>	<p style="text-align: right;">Page 212</p> <p>1 some of his claims. So, yes, again, I'm not going to 2 name names, but every expert report, general or case 3 specific that I have reviewed is in my reliance list 4 and available for you to review.</p> <p>5 Q. And, Doctor, in fact from what you're 6 saying, you can't tell me whether or not that 7 particular language that you just quoted is a him or a 8 her, correct?</p> <p>9 A. You know what, I don't recall.</p> <p>10 Q. Doctor, if you'd turn to page 40 and just 11 to sort of speed things up here for you, we're going to 12 be looking at page 40 and 42 and again, Doctor, your 13 bullet points with your numbering.</p> <p>14 Your number two, your number three, your 15 number four, five and six all begin with the same 16 phrases, plaintiffs' expert/counsels' and then proceed 17 with the statement that you would attribute to them.</p> <p>18 Again, you're not going to name --</p> <p>19 A. It's not a statement that I'm attributing 20 to them. It's statements that they have made in their 21 reports.</p> <p>22 Q. Okay. Counsels' report?</p> <p>23 A. No, plaintiffs' experts' report.</p> <p>24 Q. Okay. So what do you mean by, and let's</p>
<p style="text-align: right;">Page 211</p> <p>1 Q. Doctor, turn to page 38 if you would, 2 please, on Exhibit 7.</p> <p>3 A. Okay.</p> <p>4 Q. You again say that the basis of your 5 opinion is plaintiffs' experts' and counsel build the 6 entirety of their case based on language and statements 7 which are designed to shock but are not backed up by 8 scientific evidence.</p> <p>9 And again, this is where you've already 10 testified that these are persons that you're not going 11 to name that have made --</p> <p>12 A. Well, read a little bit more there. That 13 next person, that next one is a very specific statement 14 that you guys should be able to locate if you really 15 need a name.</p> <p>16 One expert's witness summation is as 17 follows. Ethicon's old construction mesh prolene used 18 in the TVT is not suitable for its intended application 19 as permanent prosthetic implant for stress urinary 20 incontinence because of the following reasons. He 21 lists out all those reasons.</p> <p>22 In my rebuttal I take every one of his 23 reasons and actually provide scientific literature to 24 help back up some of those claims or to help refute</p>	<p style="text-align: right;">Page 213</p> <p>1 take number two, for instance. Plaintiff's 2 expert/counsel's statement's suggests mesh degrades 3 over time. This too is patently false.</p> <p>4 A. Correct.</p> <p>5 Q. Any suggestion by plaintiffs' counsel 6 regarding mesh degradation are not supported by medical 7 literature.</p> <p>8 A. Correct.</p> <p>9 Q. Who are you referring to in those 10 sentences?</p> <p>11 A. So here's what I would say --</p> <p>12 Q. Again, I'm trying to get to are not going 13 to name plaintiffs' counsel there either?</p> <p>14 A. No. So here's what I'm going to say. If 15 we wind up in a courtroom drama here, my assertion is 16 going to be that any suggestion that plaintiffs' 17 counsel, plural, Bob, Cindy, Sue, I don't care who it 18 is, any assertion made by the plaintiffs' counsel 19 regarding mesh degradation is not supported by 20 scientific literature. That is fact. That is fact.</p> <p>21 So --</p> <p>22 MR. WALKER: Can I just ask a couple of 23 questions that I think will clarify this?</p> <p>24 MS. GAYLE: Let's go off the record.</p>

<p style="text-align: right;">Page 214</p> <p>1 (Off record discussion.)</p> <p>2 BY MS. GAYLE:</p> <p>3 Q. All right, Doctor. Again, after</p> <p>4 discussion with counsel, as you stated anything that</p> <p>5 you quoted in these reports, either Exhibit 4 or</p> <p>6 Exhibit 7 you contend is in your reliance list,</p> <p>7 correct?</p> <p>8 A. In one form or another it will be in the</p> <p>9 reliance list or it may be covered in the list of</p> <p>10 depositions that I have given in the past that you</p> <p>11 have, which again is not a complete list of</p> <p>12 depositions, but it will either be personal experience</p> <p>13 from those depositions, either Ethicon or beyond or it</p> <p>14 will be in my reliance list.</p> <p>15 Q. You're talking about the complete list of</p> <p>16 your depositions, right, Doctor?</p> <p>17 A. Well, I just said that that's not a</p> <p>18 complete list of my depositions.</p> <p>19 Q. That's what I just want to make sure</p> <p>20 you're referring to. It's your listing of depositions,</p> <p>21 because I think we've said that you have done more than</p> <p>22 ten, right?</p> <p>23 A. Yes.</p> <p>24 Q. Doctor, just a few more questions.</p>	<p style="text-align: right;">Page 216</p> <p>1 2017 study "the long-term follow-up outcome and</p> <p>2 ultrasound data presented in this study suggests</p> <p>3 that the importance of the tape resistance to</p> <p>4 elongation under load is of only significance in</p> <p>5 the first two weeks after implantation." That</p> <p>6 again is a comparison between laser kit and</p> <p>7 mechanical cut slings.</p> <p>8 BY MS. GAYLE:</p> <p>9 Q. Doctor, do you remember which of the TVT</p> <p>10 products that you had opinioned on used laser cut mesh?</p> <p>11 A. I've utilized both laser and mechanical</p> <p>12 mesh.</p> <p>13 Q. Well, with regard to the TVT, TVT-Exact</p> <p>14 and the TVT-O do you know which one used the laser cut</p> <p>15 mesh?</p> <p>16 A. I cannot tell you which meshes that I</p> <p>17 implanted at which time that were laser cut and</p> <p>18 mechanical cut. I did not do a lot of research into</p> <p>19 that to determine if there was one that I should be</p> <p>20 using because there really are no differences shown in</p> <p>21 the medical literature between the two.</p> <p>22 (Exhibit 19 - Document entitled Elongation of</p> <p>23 textile pelvic floor implants under load is</p> <p>24 related to complete loss of effective porosity,</p>
<p style="text-align: right;">Page 215</p> <p>1 MS. GAYLE: How much time do I have left?</p> <p>2 THE COURT REPORTER: You have 47 minutes.</p> <p>3 MS. GAYLE: Thank you.</p> <p>4 BY MS. GAYLE:</p> <p>5 Q. Do you believe, Doctor, that there's any</p> <p>6 difference between laser cut and mechanical cut mesh?</p> <p>7 A. If we --</p> <p>8 MR. WALKER: Object to form.</p> <p>9 THE WITNESS: If we trust the scientific</p> <p>10 literature, there is no difference in objective or</p> <p>11 subjective cure rates.</p> <p>12 We have a study from 2017 looking at</p> <p>13 mechanical cut and laser cut TVT-O midurethral</p> <p>14 slings that showed that there was no difference</p> <p>15 noted between the two groups with respect to</p> <p>16 bladder neck mobility, showing that the direction</p> <p>17 and length of vector of the movement of the</p> <p>18 bladder neck between rest and maximum Valsalva</p> <p>19 between the mechanical cut and laser group were</p> <p>20 the same, and we have long-term subjective and</p> <p>21 objective surgery outcome measures, including cure</p> <p>22 rates, reoperation and mesh exposures at two years</p> <p>23 after the surgery and they were comparable.</p> <p>24 So the long-term as quoted from Wasabe's</p>	<p style="text-align: right;">Page 217</p> <p>1 thereby favoring incorporation in scar plates.)</p> <p>2 BY MS. GAYLE:</p> <p>3 Q. Doctor, I think you just mentioned your</p> <p>4 -- the elongation and I'm going to hand you what's been</p> <p>5 marked as Exhibit 19. It's an article by Otto.</p> <p>6 Are you familiar with that article,</p> <p>7 Doctor?</p> <p>8 A. I think I've seen this, yes.</p> <p>9 Q. I did not again find it in your report or</p> <p>10 your materials. If it is excluded, would there have</p> <p>11 been a particular reason why you would have excluded</p> <p>12 it?</p> <p>13 A. No.</p> <p>14 Q. And, Doctor, when we talked about the</p> <p>15 pore sizes of materials, what was the microns that you</p> <p>16 said that you felt would be suitable in your opinion</p> <p>17 for a mesh product?</p> <p>18 A. Well, what's listed in the scientific</p> <p>19 literature is that 75 microns or above is considered a</p> <p>20 macroporous polypropylene mesh.</p> <p>21 Q. So it would be your opinion that</p> <p>22 something like 79 microns would be an adequate pore</p> <p>23 size?</p> <p>24 MR. WALKER: Object to form.</p>

<p style="text-align: right;">Page 218</p> <p>1 THE WITNESS: Well, an adequate pore size</p> <p>2 for what.</p> <p>3 BY MS. GAYLE:</p> <p>4 Q. Meaning to allow for tissue ingrowth for</p> <p>5 a good response?</p> <p>6 A. Well, 79 microns is not the pore size of</p> <p>7 any of the materials that we're speaking about today.</p> <p>8 Q. I'm just trying to get to what you think</p> <p>9 would be a good pore size for a good response in your</p> <p>10 opinion?</p> <p>11 MR. WALKER: Object to form.</p> <p>12 THE WITNESS: Well, I'll answer with the</p> <p>13 same response. 79 microns is not the pore size of</p> <p>14 any of the materials that we've talked about</p> <p>15 today.</p> <p>16 I'm here today to talk about Prolift,</p> <p>17 Prolift+M, Gynemesh, TVT, TVT-Exact and TVT-O and</p> <p>18 those all use polypropylene mesh which is defined</p> <p>19 as having a pore size of greater than 75 microns,</p> <p>20 but those materials have larger pore sizes than</p> <p>21 75 microns.</p> <p>22 BY MS. GAYLE:</p> <p>23 Q. Do you know what the pore size of TVT is?</p> <p>24 A. I think it's about 1.3.</p>	<p style="text-align: right;">Page 220</p> <p>1 Mesh Contraction and it's by Benjamin Feiner. Do you</p> <p>2 know Dr. Feiner?</p> <p>3 A. No.</p> <p>4 Q. Do you know Christopher Maher?</p> <p>5 A. I don't know them personally. I have</p> <p>6 heard their names. I don't know them personally.</p> <p>7 Q. And again, Doctor, we've talked about in</p> <p>8 your materials that you may have left off an article</p> <p>9 from one author or another.</p> <p>10 In regard to Dr. Feiner you did that.</p> <p>11 You included some articles but not this article. Was</p> <p>12 there a specific reason why you wouldn't have included</p> <p>13 this article?</p> <p>14 A. This article represents less than two</p> <p>15 years of scientific data whereas the report that I have</p> <p>16 listed in -- or the study that I have listed in my</p> <p>17 report is a 17 year follow-up looking at shrinkage.</p> <p>18 So I tend to, as I've stated several</p> <p>19 times today, trust long-term randomized controlled</p> <p>20 Cochrane database type procedures that give us a very</p> <p>21 long-term outlook on things.</p> <p>22 So I tend to trust what's going on with a</p> <p>23 study looking at a 17 year follow-up more than I do</p> <p>24 something that is less than two years.</p>
<p style="text-align: right;">Page 219</p> <p>1 Q. Translating into microns?</p> <p>2 A. Sorry 1.3 millimeters.</p> <p>3 Q. Can you translate that to microns?</p> <p>4 A. I can do a --</p> <p>5 Q. Would it be roughly say --</p> <p>6 A. I'm going back to my --</p> <p>7 Q. -- fourteen the times of 75 microns.</p> <p>8 Does 1300 microns sound right?</p> <p>9 MR. WALKER: Come on, Doctor, move the</p> <p>10 decimal.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MS. GAYLE:</p> <p>13 Q. Okay. And, Doctor, is the basis for your</p> <p>14 opinion regarding the good pore size, 75 microns, is</p> <p>15 that the Ahmet article that you cited in your</p> <p>16 materials?</p> <p>17 A. Uh-huh.</p> <p>18 (Exhibit 18 - Document entitled Vaginal Mesh</p> <p>19 Contraction.)</p> <p>20 BY MS. GAYLE:</p> <p>21 Q. Doctor, handing you what's been marked as</p> <p>22 Exhibit 18, my last exhibit.</p> <p>23 A. All right.</p> <p>24 Q. Doctor, this article is entitled Vaginal</p>	<p style="text-align: right;">Page 221</p> <p>1 And specifically I'm referring to</p> <p>2 Nielson's study, Lowe's study and others here that</p> <p>3 concluded that shrinkage and comprise of the TVT sling</p> <p>4 does not occur.</p> <p>5 Q. Do you know whether Nielsen, the one that</p> <p>6 you just referred to is a paid expert for the defendant</p> <p>7 in this litigation?</p> <p>8 A. I don't know if Nielsen or Lowe is.</p> <p>9 MR. WALKER: Object to form.</p> <p>10 THE WITNESS: I don't know if Dietz is,</p> <p>11 but Lowe and Dietz came to the same conclusion so</p> <p>12 I don't know who are experts on either side.</p> <p>13 BY MS. GAYLE:</p> <p>14 Q. Would it be important for you to know</p> <p>15 whether or not they were an expert for the defendant</p> <p>16 when evaluating their literature?</p> <p>17 MR. WALKER: Object to form.</p> <p>18 THE WITNESS: No, I don't care if they're</p> <p>19 an expert for the plaintiffs or the defendant when</p> <p>20 I evaluate a piece of literature.</p> <p>21 BY MS. GAYLE:</p> <p>22 Q. Do you believe that being paid by either</p> <p>23 one side or the other could have a bias on a particular</p> <p>24 author of a medical paper?</p>



Page 222	Page 224
<p>1 MR. WALKER: Object to form.</p> <p>2 THE WITNESS: Well, you know, long-term</p> <p>3 randomized controlled trials, Cochrane database</p> <p>4 are there expressly to eliminate bias.</p> <p>5 So again, that's why I tend to trust the</p> <p>6 articles that I have in my report versus the</p> <p>7 articles that you're presenting to me today, to</p> <p>8 eliminate bias.</p> <p>9 BY MS. GAYLE:</p> <p>10 Q. And do you know Dr. Nielsen personally?</p> <p>11 A. No, I do not.</p> <p>12 Q. Doctor, earlier we talked about some of</p> <p>13 your literature that you had -- excuse me -- articles</p> <p>14 that you had written in your CV that you had pointed</p> <p>15 out that were relevant today. Just a clean up question</p> <p>16 with regard to that.</p> <p>17 Were any of those studies funded by a</p> <p>18 pharmaceutical or medical device corporation?</p> <p>19 A. I believe that I have in my CV the only</p> <p>20 actual funding that I have obtained from a medical</p> <p>21 device corporation. Just to be clear and transparent,</p> <p>22 I will find that for you so that we can put that on the</p> <p>23 record.</p> <p>24 This was a grant that I received in 2009.</p>	<p>1 midurethral sling into a tunnel that is .5 centimeters,</p> <p>2 that mesh is going to roll and it's going to band</p> <p>3 because you are forcing a one centimeter wide piece of</p> <p>4 mesh into a half centimeter wide tunnel.</p> <p>5 It is basic scientific understanding. So</p> <p>6 what I teach my residents to do is make sure that the</p> <p>7 tunnels leading back, the tunnels leading between the</p> <p>8 area of the midurethra and the area of the descending</p> <p>9 pubic rami be the same width as the midurethral sling</p> <p>10 so that banding and rolling can't occur.</p> <p>11 And, yes, I think the rest of it is</p> <p>12 banding and rolling can occur either from over</p> <p>13 tensioning at the time of surgical implant or it can</p> <p>14 occur as a result of a surgical implant not being</p> <p>15 appropriately sutured and tacked into its surrounding</p> <p>16 tissues to prevent rolling of the edges.</p> <p>17 Q. But you do not think that it would be due</p> <p>18 to a product defect?</p> <p>19 A. No, I do not.</p> <p>20 Q. And, Doctor, with regard to fraying, you</p> <p>21 do not think that fraying would occur due to a product</p> <p>22 defect, correct?</p> <p>23 A. In all of the pieces of mesh that I have</p> <p>24 removed in my career, the only fraying of a mesh that I</p>
Page 223	Page 225
<p>1 The total amount was \$10,000. That was from Astellas</p> <p>2 Corporation, and that was in my design of a cystoscopy</p> <p>3 teaching models for residents and fellows.</p> <p>4 Outside of that, I've received no funding</p> <p>5 from medical device corporations for any of my</p> <p>6 publications.</p> <p>7 Q. Thank you, Doctor. And my last couple of</p> <p>8 questions here, just clean up questions. Have you ever</p> <p>9 heard the term banding?</p> <p>10 A. Yes.</p> <p>11 Q. And, Doctor, do you think that the</p> <p>12 phenomenon of banding takes place because the surgeon</p> <p>13 who is putting in the transvaginal mesh product pulled</p> <p>14 too tightly on the mesh itself?</p> <p>15 A. I think that is one of the reasons that</p> <p>16 banding can occur. I think that specific to</p> <p>17 midurethral slings, that what I teach my residents in</p> <p>18 the operating room every time we do a dissection for</p> <p>19 mesh is that the tunnels leading from the area of the</p> <p>20 midurethra back to the descending pubic rami, which is</p> <p>21 where the transobturator sling as well as the</p> <p>22 retropubic sling pass, that tunnel must be dissected to</p> <p>23 the same width as the midurethral sling.</p> <p>24 If we place a one centimeter wide</p>	<p>1 have observed was at my own hands where I was trying to</p> <p>2 cut and remove a piece of mesh.</p> <p>3 Outside of that, in all of the mesh that</p> <p>4 I have seen inside too, whether it was being removed or</p> <p>5 not, I've never seen any evidence of fraying of the</p> <p>6 mesh.</p> <p>7 MS. GAYLE: I'll reserve the balance of</p> <p>8 my time. If we could take a short break before</p> <p>9 you start with your questions if you don't mind.</p> <p>10 (Recess taken.)</p> <p>11 EXAMINATION BY MR. WALKER:</p> <p>12 Q. Good afternoon, Doctor.</p> <p>13 A. Good afternoon.</p> <p>14 Q. I don't think I ever introduced myself on</p> <p>15 the record initially, but I'm Jordan Walker</p> <p>16 representing Ethicon and Johnson &amp; Johnson. I have</p> <p>17 just a few followup questions for you.</p> <p>18 A. Sure.</p> <p>19 Q. This won't take long. Let's go back to</p> <p>20 the very beginning of the deposition.</p> <p>21 Do you remember one of the earlier</p> <p>22 questions that you were asked had to do with whether or</p> <p>23 not you relied on any information pertaining to slings</p> <p>24 in the formulation of your Prolift report.</p>

<p style="text-align: right;">Page 226</p> <p>1 Do you remember that question?</p> <p>2 A. I do.</p> <p>3 Q. And then the inverse of that question was</p> <p>4 asked as well. Do you remember that?</p> <p>5 A. I do, yes.</p> <p>6 Q. And is it fair to say that your answer</p> <p>7 reflected the fact that a randomized controlled trial</p> <p>8 for TVT doesn't really inform you as it pertains to</p> <p>9 Prolift, is that fair?</p> <p>10 MS. GAYLE: Objection to leading.</p> <p>11 THE WITNESS: That's correct.</p> <p>12 BY MR. WALKER:</p> <p>13 Q. Doctor, both sling and the prolapse</p> <p>14 products are made of prolene material, correct.</p> <p>15 A. That's correct.</p> <p>16 Q. And, Doctor, I'm going to show you a</p> <p>17 position statement issued by AUGS/SUFU in 2018. You</p> <p>18 have seen this before and have relied on it, correct?</p> <p>19 A. I have.</p> <p>20 Q. This doesn't pertain to prolapse meshes</p> <p>21 per se, it's addressing full length midurethral slings,</p> <p>22 correct?</p> <p>23 A. Correct.</p> <p>24 Q. Doctor, do you see the first paragraph,</p>	<p style="text-align: right;">Page 228</p> <p>1 MS. GAYLE: Objection to form.</p> <p>2 BY MR. WALKER:</p> <p>3 Q. Are you currently licensed to practice</p> <p>4 medicine in the state of Tennessee?</p> <p>5 A. Yes, I am.</p> <p>6 Q. I just wanted to make that clear.</p> <p>7 A. All right.</p> <p>8 Q. A number of questions were asked about</p> <p>9 your reliance list and your reference to -- strike</p> <p>10 that.</p> <p>11 A number of questions were asked</p> <p>12 initially in the deposition about whether you reviewed</p> <p>13 expert reports that had been issued by plaintiffs'</p> <p>14 counsel in the pelvic mesh litigation.</p> <p>15 A. Yes.</p> <p>16 Q. Do you recall that?</p> <p>17 A. Yes.</p> <p>18 Q. And you have, in fact, reviewed a number</p> <p>19 of different expert reports issued by plaintiffs'</p> <p>20 counsel in this litigation?</p> <p>21 MS. GAYLE: Objection, leading.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. WALKER:</p> <p>24 Q. And are those reports reflected on your</p>
<p style="text-align: right;">Page 227</p> <p>1 just the bold heading right there where it says</p> <p>2 polypropylene material is safe and effective as a</p> <p>3 surgical implant?</p> <p>4 A. Correct.</p> <p>5 Q. Have I read that correctly?</p> <p>6 A. Yes.</p> <p>7 Q. Doctor, is that the sort of information</p> <p>8 pertaining to the prolene, polypropylene material in</p> <p>9 general that is applicable and the basis for your</p> <p>10 opinions for both slings and the Prolift products?</p> <p>11 MS. GAYLE: Objection.</p> <p>12 THE WITNESS: Yes, specific crossover</p> <p>13 between my reports on sling and prolapse are</p> <p>14 related to generalizable findings of the actual</p> <p>15 material itself and not specific to the product.</p> <p>16 BY MR. WALKER:</p> <p>17 Q. So if there's medical literature or</p> <p>18 position statements or any other kinds of documents</p> <p>19 that you've reviewed that is addressing the issue of</p> <p>20 the biocompatibility of polypropylene and/or prolene,</p> <p>21 is that the type of information that would form the</p> <p>22 basis of your opinions both in the realm of slings and</p> <p>23 in the realm of prolapse repair kits?</p> <p>24 A. Yes, that's correct.</p>	<p style="text-align: right;">Page 229</p> <p>1 reliance list?</p> <p>2 A. Yes, they are.</p> <p>3 Q. And you correct me if I'm wrong here, but</p> <p>4 is it fair to say that in terms of the design defect</p> <p>5 allegations against slings if it's a sling report or</p> <p>6 against Prolift if it's a Prolift report, those design</p> <p>7 defect allegations from the plaintiffs' experts are</p> <p>8 essentially the same from report to report; is that</p> <p>9 fair?</p> <p>10 A. Yes, they're very similar.</p> <p>11 Q. So, for example, when Dr. Daniel Elliott</p> <p>12 issued a Prolift general report that you have</p> <p>13 referenced on your reliance list, that's something you</p> <p>14 would have read?</p> <p>15 A. Yes.</p> <p>16 Q. And when Uwe Klinge issued a POP general</p> <p>17 report, that's something you would have read?</p> <p>18 A. Yes.</p> <p>19 Q. In all of these -- Jerry Blaivas issued a</p> <p>20 Prolift general report. That's something that you</p> <p>21 read?</p> <p>22 A. Yes, sir.</p> <p>23 Q. So all of those reports, do they</p> <p>24 essentially contain the same design defect allegations?</p>

<p style="text-align: right;">Page 230</p> <p>1 A. Yes, they do.</p> <p>2 Q. And are those design defect allegations</p> <p>3 specifically identified in your report?</p> <p>4 A. Yes, they are.</p> <p>5 Q. And do you provide specific rebuttals in</p> <p>6 your report to those allegations?</p> <p>7 A. Yes, I do.</p> <p>8 MS. GAYLE: Objection to leading.</p> <p>9 BY MR. WALKER:</p> <p>10 Q. In your reports as noticed by plaintiffs'</p> <p>11 counsel.</p> <p>12 A. Hold on one second. Hand me back what I</p> <p>13 just gave you. I need half of that back. Sorry.</p> <p>14 Q. So in today's deposition, plaintiffs'</p> <p>15 counsel asked a number of questions about the verbiage</p> <p>16 in your report that refers to plaintiffs'</p> <p>17 experts/counsel or references to plaintiffs' counsel.</p> <p>18 When you were referring to plaintiffs'</p> <p>19 counsel, were you referring to any one particular</p> <p>20 individual?</p> <p>21 MS. GAYLE: Objection, leading.</p> <p>22 THE WITNESS: No, I'm more referring to a</p> <p>23 culmination of different plaintiffs' counsels that</p> <p>24 I have dealt with in numerous depositions that</p>	<p style="text-align: right;">Page 232</p> <p>1 MR. WALKER: Got you. Thank you.</p> <p>2 BY MR. WALKER:</p> <p>3 Q. Doctor, have all of the opinions that</p> <p>4 you've expressed in these two expert reports and those</p> <p>5 opinions that you articulated in this deposition, have</p> <p>6 those opinions been to a reasonable degree of medical</p> <p>7 certainty?</p> <p>8 A. Absolutely.</p> <p>9 MR. WALKER: Nothing further.</p> <p>10 EXAMINATION BY MS. GAYLE:</p> <p>11 Q. Doctor, just one or two short questions.</p> <p>12 You were just asked a moment ago about Dr. Elliott's</p> <p>13 report. Do you know when you may have read Dr.</p> <p>14 Elliott's report?</p> <p>15 A. Sometime within the last four to</p> <p>16 five months during the creation of these reports.</p> <p>17 Q. Doctor, I think you were asked about Dr.</p> <p>18 Blaivas' report. Would that be the same answer for his</p> <p>19 report?</p> <p>20 A. It would be the same.</p> <p>21 Q. And I think you were asking about Dr.</p> <p>22 Klinge's report. Would that be the same answer for</p> <p>23 him?</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 231</p> <p>1 I've given in the past on mesh products.</p> <p>2 BY MR. WALKER:</p> <p>3 Q. And when you say plaintiffs'</p> <p>4 expert/counsel, is that your way of communicating the</p> <p>5 overall position of the plaintiffs in this litigation</p> <p>6 is fill in the blank?</p> <p>7 MS. GAYLE: Objection, leading and form.</p> <p>8 THE WITNESS: Yes, it is. It is again a</p> <p>9 culmination of different experts as I stated</p> <p>10 earlier in her questioning. This is a culmination</p> <p>11 of expert witnesses that have provided both</p> <p>12 general and case specific testimony and I have</p> <p>13 used their claims in my report.</p> <p>14 MR. WALKER: And, counsel, there were a</p> <p>15 couple of times where you used the word duplicity</p> <p>16 in your questions, but can we stipulate you were</p> <p>17 not implying deceitfulness?</p> <p>18 MS. GAYLE: That's correct. Thank you</p> <p>19 for that. We were talking about off the record</p> <p>20 earlier repetitive language and I think that we</p> <p>21 covered that in his report where he testified that</p> <p>22 sometimes repetitive language would cross over</p> <p>23 between the two reports, and it would be</p> <p>24 identical. Thank you.</p>	<p style="text-align: right;">Page 233</p> <p>1 Q. And, Doctor, I think we looked at your</p> <p>2 invoices earlier from August the 12th until present.</p> <p>3 So we're in September 28th today.</p> <p>4 In the last two weeks, have you read any</p> <p>5 reports, expert plaintiff expert reports?</p> <p>6 A. Yes.</p> <p>7 Q. Which ones have you read in the last two</p> <p>8 weeks?</p> <p>9 A. Oh --</p> <p>10 MR. WALKER: Hang on. Let me just</p> <p>11 interrupt. To the extent you're talking about any</p> <p>12 Election Wave materials, I would ask you not to</p> <p>13 disclose any case names, but if you recall the</p> <p>14 name of the plaintiff expert.</p> <p>15 MS. GAYLE: I'm talking about with regard</p> <p>16 to this Wave 8 general designation today. I'm not</p> <p>17 talking about a designation that you hope to make</p> <p>18 or haven't made as of today.</p> <p>19 MR. WALKER: Okay.</p> <p>20 THE WITNESS: Do you mind reask ing with</p> <p>21 that clarification?</p> <p>22 BY MS. GAYLE:</p> <p>23 Q. Certainly, Doctor. With regard to</p> <p>24 reports issued today in Wave 8, your general reports,</p>

Page 234

1 Exhibit 4 and 7 that we've talked about, in the last  
2 two weeks have you read any general reports with regard  
3 to that work?

4 A. I have, but I cannot tell you specific  
5 names. Some of them have been read repetitively. Some  
6 of them have only been read once.

7 I have gone back during the course of  
8 preparing for this deposition and looked at general  
9 reports as well as read through my reports, but I  
10 cannot specify to you a specific name that I have read  
11 in the last two weeks.

12 Q. And, Doctor, you haven't certainly or I  
13 haven't received a supplemental report. So you have  
14 not supplemented your opinions in either the Prolift  
15 report found at Exhibit 4 or the TVT report found at  
16 Exhibit 7?

17 A. I have not at this point submitted  
18 supplements to either of my reports.

19 MS. GAYLE: Thank you, doctor. No  
20 further questions.

21 MR. WALKER: Thank you. Nothing further  
22 We're done.

23 FURTHER THIS DEPONENT SAITH NOT  
24 (The deposition concluded at 2:44 p.m.)

Page 235

1 C E R T I F I C A T E  
2 S T A T E O F T E N N E S S E E  
3 C O U N T Y O F K N O X

4 I, Georgette H. Mitchell, Registered  
5 Professional Reporter, Licensed Court Reporter #55 and  
6 Notary Public, do hereby certify that I reported in  
7 machine shorthand the deposition of C. BRYCE BOWLING,  
8 M.D., called as a witness at the instance of the  
9 Plaintiffs, that the said witness was duly sworn by me;  
10 that the reading and subscribing of the deposition by  
11 the witness was waived; that the foregoing pages were  
12 transcribed under my personal supervision and  
13 constitute a true and accurate record of the deposition  
14 of said witness.

15 I further certify that I am not an attorney or  
16 counsel of any of the parties, nor an employee or  
17 relative of any attorney or counsel connected with the  
18 action, nor financially interested in the action.

19 Witness my hand and seal this the 4th day of  
20 October, 2018.

21 \_\_\_\_\_  
22 Georgette H. Mitchell  
23 Registered Professional  
24 Reporter, Licensed Court  
Reporter 55, LCR expires  
6-30-20 and Notary Public  
My Commission Expires: